Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 22, 2016 5:35 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on section 5 scope of preemption
Attachments: Markey.TCSA TA.Section 5 Scope of preemption.docx

Michal – the attached TA responds to your request on section 5 scope of preemption. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 08, 2016 1:10 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - scope of preemption

HI Sven

I'm trying to come up with potential compromises on section 5 scope of preemption in the event they are needed. I'd like some TA on the attached.
Basically what I tried to do is mirror the Senate section 6 scope language. The questions I have about this are the following:

1) As a general matter, does EPA feel this is drafted as it should be if the policy goal is to preempt states from taking action on new chemicals only to the extent the actions relate to the same hazards, risks, exposures and uses subject to a SNUR? If not, what would you change to accomplish this goal?
2) My main concern with any section 5 preemption is that what is known at the time the section 5 action is taken by EPA may not be true 30 years later, yet states would still be preempted as though EPA did an exhaustive risk evaluation on that chemical. The following scenarios are intended to get at that concern:
    a. Let's say EPA considered the potential that the substance causes leukemia when it did its SNUR. What if, at some point in the future, it turns out that the chemical's chance of causing leukemia is actually much higher. Would this be considered a different hazard or risk, or the same hazard or risk because it is still a risk of leukemia?
    b. Let's say EPA considered the potential that the substance causes leukemia in children when it did its SNUR. What if, at some point in the future, it turns out that the chemical also causes cancer in workers? Would this be considered a different hazard or risk, or the same hazard or risk because it is still a risk of leukemia?
    c. Let's say EPA considered the potential that the substance causes leukemia when it did its SNUR. What if, at some point in the future, it turns out that it causes a different type of cancer or leukemia? Would this be considered a different hazard or risk, or the same hazard or risk?
    d. What about a scenario where the exposures EPA considered in the SNUR change entirely – ie EPA believed the chemical would be used in only a limited way, but 30 years later, it turns out it is

everywhere and in everything. Would this be considered a different exposure and use scenario that would allow states to regulate, even if they were regulating to address the same hazard or risk?

3) The other potential compromise I'm considering is one where the House section 5 scope applies only for 5-10 years after the NOC on the substance is submitted to EPA. After that, the preemption regime would switch to a section 6 regime. I'd be interested in your thoughts on that as well.

Thanks
Michal

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Scope of preemption

(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

(C) ~~SIGNIFICANT NEW USE~~NEW CHEMICALS.—A statute or administrative action ~~requiring the notification of a~~to prohibit or otherwise restrict the use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

(2) the hazards, exposures, risks and uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

(3) the hazards, exposures, risks and uses or conditions of uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

***

1) As a general matter, does EPA feel this is drafted as it should be if the policy goal is to preempt states from taking action on new chemicals only to the extent the actions relate to the same hazards, risks, exposures and uses subject to a SNUR? If not, what would you change to accomplish this goal?

As best we can ascertain your intent, these edits will not function as intended.

Regarding the edits to §18(a)(1)(C): These edits will significantly alter the preemptive effect of EPA issuing SNURs, relative to the current draft of the Senate bill. Under the baseline draft of the bill, the issuance of a SNUR only preempts states from issuing their own parallel notification requirements (i.e., state SNURs) and does not preempt substantive state regulation of the chemical substance. But as edited, EPA's issuance of a SNUR would not preempt states from issuing duplicative state SNURs but would potentially preempt substantive state regulation of the chemical substance. As best we can ascertain your intent in your TA request, this does not appear to be the outcome you are looking for.

It is also somewhat unclear what sort of chemicals you are trying to address under the heading of "new chemicals." Note that a new chemical stops being a new chemical as soon as EPA lists it on the Inventory. A chemical on the Inventory is an "existing chemical," regardless of whether it was ever reviewed by EPA's new chemical program.

Regarding the edits to §18(c)(3): These are problematic as drafted because EPA does not designate a particular hazard, exposure, or risk as a "significant new use." EPA designates a use of a chemical as a significant new use. Note also:

(1) EPA is on record stating that a significant new use determination "need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use." See e.g., 80 FR 57293 (September 23, 2015). The detailed consideration of potential risks or hazards is deferred until such time as somebody wants to start the significant new use and sends EPA a notice that they intend to commence manufacturing or processing for that use. By "determination," EPA means here a determination that a particular use ought to be designated as a significant new use. This is different from a risk assessment of that particular significant new use, which would occur when someone wants to start manufacturing or processing for that use.

(2) Under the Senate bill, SNURs could be issued following a determination that a new chemical substance is not likely to meet the safety standard (or that more information is necessary), but they can also be issued in other circumstances. The actual basis for issuing a SNUR is simply a consideration of the § 5(b)(2) factors (they're the § 5(a)(2) factors under current TSCA).

(3) These edits seems to confuse a determination that a significant new use (§ 5(b)(2)) ought to be established and a determination that a new chemical or an established significant new use is or is not likely to meet the safety standard. (§ 5(d)(3)). We imagine you are primarily concerned with the latter, yet the language refers to the former.

Suggested drafting to accomplish your intended objective: The following drafting edits are premised on our understanding that you intended to draft a provision whereby EPA's review of a new chemical substance under § 5(d) would come to have preemptive effect (it has no preemptive effect under the current Senate bill), but:

- Only to the extent that the § 5(d) finding is accompanied by an exercise of EPA's SNUR authority, to ensure that uses beyond the scope of consideration at the time of the new chemical review (or manufacturing/processing inconsistent with EPA-imposed restrictions) could later be reviewed as significant new uses; and
- Being clear (as with Section 6(d) actions) that states would not be preempted from taking action to address hazards, exposures, and risks that were beyond the scope of EPA's review when it evaluated the chemical as a new chemical under § 5(d).

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(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

(D) CERTAIN CHEMICAL SUBSTANCES FOUND LIKELY TO MEET THE SAFETY STANDARD.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) that is--

(I) likely to meet the safety standard, consistent with the scope of the determination made under subsection 5(d)(3)(B); or

(II) sufficiently restricted to ensure that, as restricted, it is likely to meet the safety standard, consistent with the scope of the determination made under subsection 5(d)(4)(A); and

(ii) for which all manufacturing and processing inconsistent with the restrictions imposed under subsection 5(d)(4)(A) and all uses that the Administrator did not consider in arriving at the determination under 5(d)(3)(B) or 5(d)(4)(A) have been designated as significant new use under 5(b).

***

(2) the hazards, exposures, risks and uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d);

(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5; or

(4) the hazards, exposures, risks and uses or conditions of use of such substances that are identified by the Administrator as subject to review in a determination that a chemical substance is likely to meet the safety standard

Commented [A1]: This is basically treating a § 5 "likely safe" determination equivalently to a § 6 "safe" determination, as long as EPA takes the further step of SNUR'ing all the uses that were not specifically included in the scope of the review when the chemical went through the new chemicals review and all uses that are restricted in a section 5(d)(4)(A) order. We believe this is the objective underlying your original draft, but please let us know if we are mistaken.

Note: The "effective date" proviso from § 18(a)(1)(B)(ii) is unnecessary and potentially harmful when describing § 5 restrictions, because § 5(d)(4)(A)(i)(II) automatically bans manufacture/processing except to the extent in compliance with the restrictions. We think it would be unhelpful to suggest that there could be a period when the use is occurring, prior to the effective date.

under section 5(d)(3)(B) or that certain restrictions would be sufficient to ensure that a chemical substance is likely to meet the safety standard under section 5(d)(4)(A).

Commented [A2]: Rather than trying to the use the SNUR scoping provision, which doesn't relate back to a 5(d) determination, create a new scoping provision that is tied to the 5(d) determination that certain uses are either naturally likely to meet the safety standard, or that certain regulations will suffice to ensure the uses are likely to meet the safety standard.

2) My main concern with any section 5 preemption is that what is known at the time the section 5 action is taken by EPA may not be true 30 years later, yet states would still be preempted as though EPA did an exhaustive risk evaluation on that chemical. The following scenarios are intended to get at that concern:

Per the explanation above, EPA does not make hazard and risk determinations as part of issuing SNURs. The following answers provide EPA's technical views as to whether certain hazards, risks and exposures would likely be viewed as the same as or different from other hazards, risks and exposures, independent of any specific statutory or bill text.

a. Let's say EPA considered the potential that the substance causes leukemia when it did its SNUR. What if, at some point in the future, it turns out that the chemical's chance of causing leukemia is actually much higher. Would this be considered a different hazard or risk, or the same hazard or risk because it is still a risk of leukemia?

If the newly perceived increased risk was the result of EPA identifying some sort of exposure, hazard, health endpoint, or mode of action that EPA had not previously reviewed, then this would be likely considered a different exposure, hazard, or risk.

b. Let's say EPA considered the potential that the substance causes leukemia in children when it did its SNUR. What if, at some point in the future, it turns out that the chemical also causes cancer in workers? Would this be considered a different hazard or risk, or the same hazard or risk because it is still a risk of leukemia?

The risk to workers would likely involve a different set of exposures, hazards, or risks than were reviewed when studying the risk of causing leukemia in children.

c. Let's say EPA considered the potential that the substance causes leukemia when it did its SNUR. What if, at some point in the future, it turns out that it causes a different type of cancer or leukemia? Would this be considered a different hazard or risk, or the same hazard or risk?

The risk of causing a different type of cancer or leukemia would likely be a different hazard or risk.

d. What about a scenario where the exposures EPA considered in the SNUR change entirely – ie EPA believed the chemical would be used in only a limited

way, but 30 years later, it turns out it is everywhere and in everything. Would this be considered a different exposure and use scenario that would allow states to regulate, even if they were regulating to address the same hazard or risk?

Exposure limited to a limited set of discrete use scenarios would likely be a different exposure from pervasive environmental exposure or exposure though widespread consumer goods.

3) The other potential compromise I'm considering is one where the House section 5 scope applies only for 5-10 years after the NOC on the substance is submitted to EPA. After that, the preemption regime would switch to a section 6 regime. I'd be interested in your thoughts on that as well.

As stated in its January 20 letter, the Administration supports an approach to preemption that is "appropriately limited to the particular risks that the Agency actually considered in the scope of that assessment or rulemaking." The House bill would preempt state regulation for all uses of a new chemical substance identified in a PMN even if the Agency took action to address only a subset of those uses. Per your compromise language above, the House bill's non-tailored preemption for new chemicals would cease after a period of 5-10 years, at which time there would be no preemption of state regulation for that particular substance unless and until EPA acted under Section 6.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 02, 2016 12:09 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal,
This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks,
Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 01, 2016 4:53 PM
To: Kaiser, Sven-Erik
Subject: Section 6 - quick unreasonable risk q

Here is a construct being discussed:

1) epa promulgates a rule for how risk evaluations are supposed to be conducted - study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors - the unreasonable risk "fix" is made in the rule itself.

2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 6:03 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 analysis - chemical alternatives analysis

Michal,
This TA responds to the request on doing chemical alternatives analyses.

Question: In the past you told me that EPA would as a matter of course do an analysis of the chemicals likely to be substituted for anything EPA was going to propose to ban or phase-out as part of the rule for the ban or phase-out. If I'm wrong about that pls correct my memory.

Would EPA also expect to do analysis like that when it was proposing a restriction that was not a ban or phaseout? Like a limitation on a concentration/amt? A label? A limitation on the means of disposing of the substance? Other types of restrictions?

Response: As a general matter, EPA would likely do an alternatives analysis even when proposing a restriction other than a ban or phase-out. Such analyses are important to understanding health or environmental benefits. However, in limited circumstances, a proposal for very minor restrictions may not be informed by such an analysis.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

> **From:** Freedhoff, Michal (Markey)
> [mailto:Michal_Freedhoff@markey.senate.gov]
> **Sent:** Wednesday, March 23, 2016 7:12 PM
> **To:** Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
> **Subject:** Section 6 analysis - chemical alternatives analysis
>
> Sven
>
> In the past you told me that EPA would as a matter of course do an analysis of the chemicals likely to be substituted for anything EPA was going to propose to ban or phase-out as part of the rule for the ban or phase-out. If I'm wrong about that pls correct my memory.
>
> Would EPA also expect to do analysis like that when it was proposing a restriction that was not a ban or phaseout? Like a

limitation on a concentration/amt? A label? A limitation on the means of disposing of the substance? Other types of restrictions?

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 2:26 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on Section 6 cost considerations
Attachments: Updated Table on Cost Considerations.docx

Michal – please see the requested TA in the updated chart. The new options are labeled Senate offer and Supplemented Senate Offer. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 07, 2016 2:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Section 6 cost considerations

In the same spirit and on the same timeframe as the others I've sent today, can this redline to what was sent to the House last week AND the version of the language that was sent to the House last week be ranked/added to the table from the 01/05/16 TA?

Thanks
Michal

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Question: Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Answer:

We do not think a general direction to take action "consistent with" the referenced policy document would reliably lead to a more stringent outcome than current S. 697, which clearly directs EPA to achieve the more stringent of: (1) What is necessary to meet the safety standard and (2) Exposure reduction to the maximum extent practicable. First, the PBT policy statement at 64 FR 60202 (1999) describes actions that EPA will generally take under section 5 as to PBTs, but it also clearly states that the document provides "general guidance" that is not binding on EPA or outside parties, so EPA could take actions other than the generally recommended control actions that would be consistent with the policy. Second, your draft language references successor policy statements, without circumscribing the content of such statements, so the language ultimately provides little bounding for EPA decisions with respect to new PBT chemicals. Third, since legislative history would reflect that the new language was a change from a strict prior directive to achieve more than the Section 6 safety standard, there would likely be an implication from this revision that Congress intended to allow EPA more flexibility.

You also ask for suggested tweaks, but we would need to better understand your policy objectives, and the perceived deficiencies of the current bill text, to provide language.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 5:24 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request on section 6 implementation dates for bans/phaseouts
Attachments: Markey.TSCA TA.section 6 dates for bans and phaseouts.docx

Michal,
This responds to your TA request on section 6 implementation dates for bans and phaseouts. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 07, 2016 1:19 PM
To: Kaiser, Sven-Erik
Subject: TA request - Markey implementation dates for bans/phaseouts

Sven

Again, for after the other pending TA requests, and again, in the spirit of trying to come up with some alternative options in case they are needed. This is an effort to clarify the industry compliance date language but provide an explicit way for EPA to consider long product cycles (like automobiles, for example).

Pls let me know of any workability or other concerns.

Thanks
Michal

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TA Request: This is an effort to clarify the industry compliance date language but provide an explicit way for EPA to consider long product cycles (like automobiles, for example). Please let me know of any workability or other concerns.

(a) EFFECTIVE DATE.--(1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect. ~~which date shall be as soon as feasible~~ and dates by which compliance is mandatory, which

(A) shall be as soon as practicable, but which shall require full implementation of all restrictions not later than 4 years after the date of promulgation of the rule, except in a case of a use exempted under subsection(g);

(B) shall provide for a reasonable transition period, including for restrictions that impose a ban or phase-out of the chemical substance, subject to the condition that full compliance with all restrictions shall be required within the timeframe established in (a)(1)(A);

(C) as determined by the Administrator, may vary for different affected persons; and

(D) following a determination by the Administrator that compliance is technologically or economically infeasible within the timeframe specified in subparagraph (A), shall provide up to an additional 18 months for compliance to be mandatory.

(6)(g)(3)

ANALYIS IN CASE OF BAN OR PHASE_OUT - In determining whether an exemption should be granted for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and non-quantifiable costs and benefits of the 1 or more alternatives to the chemical substance the Administrator determines to be technically and economically feasible and most likely to be used in place of the chemical substance under the conditions of use, and, for an exemption from a proposed ban or phase-out of a use of a chemical substance in an article, whether the ban or phase-out would require the re-design of the article or another article of which it is a component and whether the proposed ban or phase-out can be practicably accomplished for the use of the chemical substance in such the articles by the date required by the rule ~~the Administrator specifies to be mandatory~~.

~~(D)~~

Commented [A1]: Edits move this idea from (A) to (B), where it seems to more squarely prevent arguments that transition timeframes could extend beyond 4 years.

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Commented [A2]: It is difficult to evaluate this text without knowing whether articles are addressed elsewhere in the bill. Is this text in lieu of the kinds or articles analysis that has factored into the basic rulemaking decisionmaking in the bills, or in addition to it? In addition, note that, while your goal is to provide "an explicit way for EPA to consider long product cycles", this provision would not expand EPA's authority to grant an exemption, since the grounds for exemption are specified elsewhere (6(d)(5)(A) in 697). If the latter, not clear why it is necessary. (On a related note: we have always found this 6(g)(3) provision a little confusing, since to some extent it seems to require in the exemption context re-analysis of the underlying rule. This raises the question in our minds as to whether this is the best place to put this provision.) That all said, with probably could be workable.

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Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 22, 2016 5:44 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on Section 6 Implementation Dates
Attachments: Markey.TSCA TA.Section 6 implementation.docx

Michal – see the attached TA that responds to your request on section 6 implementation dates. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 10, 2016 at 9:29:18 PM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Section 6 Implementation Dates

Sven

As I recall, the proposed asbestos ban had numerous components attached to it. Some were short time horizon, some were longer. Some phase-outs going forward might begin starting in year 2 after the rule effective date, but not be fully implemented until say year 6. These sorts of characterizations have been made and used to raise concerns about the Senate "industry implementation date" language, which calls for EPA to write regulations that are implemented as soon as practicable, but no later than 4 years after the effective date, with an up to 18 month extension.

My questions to you are:

1) Would EPA be able to easily use its exemption authority in the event that a rule directed at some products containing a chemical required a longer timeframe for complete implementation than 5.5 years, while keeping the rest of the products subject to the rule within the 5.5 total years?

2) does EPA interpret the Senate language, as applied to a gradual phaseout of a chemical, to require the COMPLETE phaseout within 5.5 years, or for industry to BEGIN phasing out the chemical within 5.5 years? What does "implementation" mean in the context of a rule that changes over time? To the extent that there could be a phaseout that needs to take longer than 5.5 years (say for an auto-related thing where the product cycles are longer than 5.5 years at times), can EPA use its exemption authority to extend the timeframe in appropriate circumstances?

3) can EPA currently envision scenarios in which a rule, ban, phaseout, etc would take longer than 5.5 years and for which EPA could NOT easily justify an exemption in order to make part or all of the rule in question be completed at a later time?

4) to the extent that these questions - or other EPA views on the provisions - raise workability or other challenges, can EPA suggest solutions that do not undermine the intent of the provision (like if the solutions end up enabling all EPA rule implementation dates to be extended beyond 5.5 years)?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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As I recall, the proposed asbestos ban had numerous components attached to it. Some were short time horizon, some were longer. Some phase-outs going forward might begin starting in year 2 after the rule effective date, but not be fully implemented until say year 6. These sorts of characterizations have been made and used to raise concerns about the Senate "industry implementation date" language, which calls for EPA to write regulations that are implemented as soon as practicable, but no later than 4 years after the effective date, with an up to 18 month extension.

My questions to you are:

1) Would EPA be able to easily use its exemption authority in the event that a rule directed at some products containing a chemical required a longer timeframe for complete implementation than 5.5 years, while keeping the rest of the products subject to the rule within the 5.5 total years?

EPA Response: The exemption authority in section 6(d)(5) is clearly available to allow for longer implementation periods than 5.5 years for chemicals in particular products, while keeping the rest of the products subject to the rule within the 5.5 year total. Section 6(d)(2)(A)(ii)(I) expressly creates an exception from the 4-year timeframe established in that subclause (and by extension from the additional 18 months allowable under section 6(d)(2)(A)(ii)(IV)) for chemicals subject to (d)(5) exemptions.

2) does EPA interpret the Senate language, as applied to a gradual phaseout of a chemical, to require the COMPLETE phaseout within 5.5 years, or for industry to BEGIN phasing out the chemical within 5.5 years? What does "implementation" mean in the context of a rule that changes over time? To the extent that there could be a phaseout that needs to take longer than 5.5 years (say for an auto-related thing where the product cycles are longer than 5.5 years at times), can EPA use its exemption authority to extend the timeframe in appropriate circumstances?

EPA Response: We believe the application of section 6(d)(2)(A)(2) to chemical phaseouts (and phased requirements generally) is ambiguous. The net effect of § 6(d)(2)(A)(ii)(I) and (IV) of the Senate bill is that, unless EPA issues an exemption under 6d5, EPA must make "compliance" with section 6 rule requirements "mandatory" within 5.5 years. We believe that could be interpreted as requiring to EPA to ensure that any phased obligations are completed within that timeframe, or that EPA can allow up to 5.5 years before the regulated community needs to being implementation of the phased obligations.

We note a related ambiguity as to the interaction between § 6(d)(2)(A)(ii)(I), which establishes the general requirement that compliance must be mandatory "as soon as practicable, but not later than 4 years after the date of promulgation of the rule. . . .", and § 6(d)(2)(A)(ii)(II) provides that a rule establishing a ban or phase must "implement the ban or phaseout in as short a period as practicable." This second provision calls into question whether the 4-year and 5.5-year timeframes are applicable to rules establishing bans or phaseouts. Because § 6(d)(2)(A)(ii)(I) *already* requires that compliance be mandatory as soon as practicable for *all* section 6 rules, it might be argued that §

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6(d)(2)(A)(ii)(II) is superfluous if it does not relieve ban and phaseout rules from the specific timeframes. An alternative reading under which the 5.5-year limits apply to ban and phase out rules would be that the all requirements, including ban and phaseout requirements, must be "mandatory" within 5.5 years per § 6(d)(2)(A)(ii)(I) (and IV) (meaning only that compliance with a phaseout must have commenced by that time), but that a ban or phase-out must actually be completed ("implemented") in as short a period as practicable (although this could be beyond year 5.5).

Per the answer to question 1, regardless of how these provisions are interpreted, EPA could use its exemption authority to extend the timeframe in appropriate circumstances.

3) can EPA currently envision scenarios in which a rule, ban, phaseout, etc would take longer than 5.5 years and for which EPA could NOT easily justify an exemption in order to make part or all of the rule in question be completed at a later time?

EPA Response: Each situation would have to be judged on its own facts as applied to the section 6(d)(5) criteria. For example, if an entity requested an exemption based on section 6(d)(5)(A)(i)(III), EPA would have to determine whether the use in question is critical or essential, and whether no technically and economically feasible alternative to the chemical is available. We cannot say whether EPA could easily justify any particular exemption.

4) to the extent that these questions - or other EPA views on the provisions - raise workability or other challenges, can EPA suggest solutions that do not undermine the intent of the provision (like if the solutions end up enabling all EPA rule implementation dates to be extended beyond 5.5 years)?

EPA Response: The following is our attempt to implement what we understand to be your policy objective:

"(2) SCOPE.—

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

"(i) may apply to mixtures containing the chemical substance, as appropriate;

"(ii) shall include dates by which compliance is mandatory, which—

"(I) shall be as soon as practicable, but require full implementation of all restrictions, including any phase-outs or other phased or multi-step restrictions, not later than 4 years after the date of promulgation of the rule, except in the case of a use exempted under paragraph (5); and

~~"(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable; and~~

"(III) as determined by the Administrator, may vary for different affected persons; and

"(IIIV) following a determination by the Administrator that compliance is

Commented [A1]: This appears largely superfluous under existing drafting and seems to be completely superfluous in light of the suggested edits to (I); if retained, it could cause confusion as the applicability of the timeframes in (I) to bans and phaseouts.

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technologically or economically infeasible within the timeframe specified in subclause (I). shall provide up to an additional 18 months for compliance to be mandatory:

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 25, 2016 4:24 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on section 6 replacement parts
Attachments: Markey.TSCA TA.section 6 replacement parts.docx

Michal,
This responds to your technical assistance requests on section 6 replacement parts including the followup question about child specific items. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On Feb 8, 2016, at 6:53 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Additional question on this topic.

I know there is an MOU btw FDA and CPSC that describes the regulatory process for BPA in baby bottles. Does the same MOU cover the pthalates in the baby bottle nipples? If not, would that fall under "replacement parts" authority?

Would sippy cup lids or straws for straw cups fall under that authority, or is all of this FDA?

You can see where I'm going with this - if there are other examples I should be thinking about in addition to the couch seat cover, esp if there is a child-specific one, do let me know.

Thanks

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Monday, February 8, 2016 5:18 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA Request on replacement parts

Michal – I'll run the additional info by folks and see how that changes things. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 08, 2016 5:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on replacement parts

Thanks Sven

In response to the comments – there is no broader document that exists, let alone that can be sent, but assume that we are talking about a section 6 provision.

The House language exempts ALL replacement parts designed prior to the effective date – and thus captures all replacement parts MANUFACTURED before the effective date as well.

I am trying to find a way to soften the House language, so that it captures the car brake pad or airplane engine part, but NOT the replacement couch seat cushion cover or replacement pacifier nipple. You guys sent me an earlier draft that would allow EPA to exempt replacement parts designed before the effective date following an affirmative finding that is similar to the language I sent. HOWEVER:

1) The House did not like that one bit. ☺
2) Even if the House did like that or my version, one would STILL presumably want to ensure that replacement parts that were manufactured prior to the effective date are exempted, even if such a finding (affirmative or not) were made.
3) That is why any final provision that doesn't exempt ALL replacement parts designed prior to the effective date would need the Senate text as well.

So what I am trying to propose is
- Manufactured by stays exempted
- Can we find a "designed by" provision that includes a presumption that the part would be exempted, UNLESS EPA makes a finding? If what I sent you doesn't do it, please suggest an alternative, and if you don't think your comment A3 works for that purpose, pls let me know.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 08, 2016 5:07 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on replacement parts

Michal,
Attached please find technical assistance that responds to your request on replacement parts. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 02, 2016 10:29 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Hi Sven

Your past TA provided an option to allow EPA to exempt replacement parts designed prior to the effective date of a TSCA regulation from that regulation if EPA found that the replacement parts would not be impracticable to replace/redesign. After receiving feedback from colleagues, I have re-drafted it to make the presumption be exemption, rather than the presumption being non-exemption. Can you take a look, suggest any changes and describe any concerns you might have with implementation?

Thanks
Michal

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(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations:

(iv) shall exempt replacement parts identified by a manufacturer during the rulemaking that are designed prior to the effective date of the rule, unless the Administrator finds

(1) that it is practicable to manufacture such ~~the~~ replacement parts that comply with the requirements of the rule and that can be used in ~~are not impracticable to redesign or replace without redesigning~~ the articles of which they are components without redesign of the articles, or

(2) such replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations:

Commented [A1]: Note that this limitation is not in (iv). Your cover email indicates an intent to exempt all replacement parts that are manufactured prior to the rule, but (iii) exempts them only if the article was first manufactured prior to the rule. If you are looking for parallelism between (iii) and (iv), you should probably either drop this language in (iii) or add it to (iv). If it is retained, we note that the "first" in this language is confusing. An article is presumably manufactured only once. Presumably, "first" refers to the *type* of article, so that a replacement part for an article manufactured after the rule date would be exempt if it was one of a series of identical or similar articles first manufactured prior to the rule date, but the meaning is not 100% clear.

Commented [A2]: "that are" added for the sake of parallelism with (iii).

Commented [A3]: This "designed by" approach – especially in conjunction with the effective date cut-off -- creates some implementation challenges, which we have addressed in part through the addition of the "identified by a manufacturer" language. As originally drafted, there was no mechanism by which EPA would know during the rulemaking what replacement parts were designed prior to the effective date and thus subject to the analysis prescribed by (1) and (2). In addition, once a rulemaking was completed, EPA would likely not know what parts were actually subject to any exemption. The addition of the "identified" language partly remedies these issues.

Even with this language, though, implementation issues would remain. EPA would need to solicit the industry identifications during development of a section 6 rule proposal, since relying on the comment process for the identifications could present notice and comment vulnerabilities in the final rule. The language we have added allows EPA to do that, but that would not account for replacement parts that are designed later in the rulemaking process, or for replacement parts that are designed after the promulgation date but prior to the effective date. For that latter scenario, it is hard to see how EPA could comply with an obligation to exempt replacements parts in a rulemaking that do not yet exist during the rulemaking process. While these issues could be solved in various ways – e.g., changing "effective date" to "promulgation date" would address the issues created by parts designed following promulgation – we have not provided drafting TA because solutions would involve policy judgments.

Commented [A4]: No comma in (iii)

Commented [A5]: The original wording was probably ok, but this seems more tied to the statutory concepts and avoids a limitation to redesign or replacement.

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Question (Michal) on Replacement Parts:

In response to the comments – there is no broader document that exists, let alone that can be sent, but assume that we are talking about a section 6 provision.

The House language exempts ALL replacement parts designed prior to the effective date – and thus captures all replacement parts MANUFACTURED before the effective date as well.

I am trying to find a way to soften the House language, so that it captures the car brake pad or airplane engine part, but NOT the replacement couch seat cushion cover or replacement pacifier nipple. You guys sent me an earlier draft that would allow EPA to exempt replacement parts designed before the effective date following an affirmative finding that is similar to the language I sent. HOWEVER:

1) The House did not like that one bit. J
2) Even if the House did like that or my version, one would STILL presumably want to ensure that replacement parts that were manufactured prior to the effective date are exempted, even if such a finding (affirmative or not) were made.
3) That is why any final provision that doesn't exempt ALL replacement parts designed prior to the effective date would need the Senate text as well.

So what I am trying to propose is

- Manufactured by stays exempted
- Can we find a "designed by" provision that includes a presumption that the part would be exempted, UNLESS EPA makes a finding? If what I sent you doesn't do it, please suggest an alternative, and if you don't think your comment A3 works for that purpose, pls let me know.

[additional question]

I know there is an MOU btw FDA and CPSC that describes the regulatory process for BPA in baby bottles. Does the same MOU cover the pthalates in the baby bottle nipples? If not, would that fall under "replacement parts" authority?

Would sippy cup lids or straws for straw cups fall under that authority, or is all of this FDA?

You can see where I'm going with this - if there are other examples I should be thinking about in addition to the couch seat cover, esp if there is a child-specific one, do let me know.

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EPA Response:

Attached are our technical comments on the bill text you sent us.

With respect to your additional questions:

TSCA excludes from the "chemical substance" definition any food or food additive as defined under the Federal Food, Drug, and Cosmetic Act (TSCA section 3(2)(B)(vi)). Because the FFDCA is implemented by FDA, EPA generally defers to FDA on the scope of this exclusion. Thus, without consulting with FDA, we cannot give a definitive answer as to whether certain items are or are not covered by TSCA.

That said, we believe that the specific items you identify (baby bottle nipples, sippy cups and straws) would most likely be considered foods within the meaning of the FFDCA and therefore outside the scope of TSCA regulation, if the regulatory concern is with migration of substances from those items into food. In addition, although we do not have particular expertise on the FDA/CPSC MOU, it appears to us that regulation to prevent or address migration of phthalates into milk or formula from baby bottle nipples would be covered by the MOU. In any event, coverage under MOU should not be relevant to whether substances in these items are chemical substances under TSCA; that determination would turn on the scope of the FFDCA definition of "food", regardless of how FDA and CPSC have chosen to coordinate their authorities for other items or substances.

Other examples you may wish to think about include replacement parts for other non-food children's products like safety seats, strollers, etc.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 22, 2016 1:06 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request on section 8 - nomenclature
Attachments: Markey.TSCA TA.Nomenclature..docx

Michal,
The attached TA responds to your request about the section 8 nomenclature issues raised by commenters. This TA might help with the section 8 TA request last night. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 6:06 AM
To: Kaiser, Sven-Erik
Subject: TA request - nomenclature

Hi Sven

Not sure if your team saw the attached. I would like your views on whether senate 8 would preclude epa requiring PMNS or issuing SNURS for short chain paraffins or nanomaterials as this blog speculates it would. Thanks.

http://switchboard.nrdc.org/blogs/drosenberg/whats_in_that_black_box_inside.html?utm_source=twitterfeed&utm_medium=twitter

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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Question:
Not sure if your team saw the attached. I would like your views on whether senate 8 would preclude epa requiring PMNS or issuing SNURS for short chain paraffins or nanomaterials as this blog speculates it would. Thanks.

http://switchboard.nrdc.org/blogs/drosenberg/whats_in_that_black_box_inside.html?utm_source=twitterfeed&utm_medium=twitter

EPA Response:
Commenters on the nomenclature provision have raised some valid points, but they somewhat overstate the scope of the chemical identity issues that are implicated by the nomenclature provisions. The nomenclature provisions relate primarily to Class 2 chemical substances. Overall, EPA would construe the first part of the nomenclature provisions (8(b)(3)(A)) as merely requiring EPA to maintain currently ongoing naming practices with respect to Class 2 chemical substances. With respect to 8(b)(3)(A)(i) and (ii), EPA believes that this would be a strong interpretation.[1] With respect to 8(b)(3)(A)(iii) (statutory mixtures), commenters have a reasonable cause for concern about potential alternative interpretations, as described below.

EPA would construe the second part of the nomenclature provisions (8(b)(3)(B)) as essentially being inoperative because the obligations there are conditioned on circumstances that EPA believes would not arise. However, as with 8(b)(3)(A)(iii), commenters have reasonable cause for concern about potential alternative interpretations.

The Nomenclature Provisions Relate Primarily to Class 2 Substances

At the outset, EPA believes that the issues likely to arise under 8(b)(3) relate more to Class 2 chemical substances than Class I substances. The nomenclature provisions are confusingly drafted and certain portions of them could be the basis of future stakeholder arguments that certain Class 2 chemical substances do not require PMN review, on the grounds that they are or should be treated as already being on the Inventory. Recall that Class 2 chemical substances are named as discrete entries on the Inventory even though they lack a defined molecular structure, whereas Class 1 chemical substances are always identified based on their exact molecular structure. The core concern that seems to be motivating the nomenclature provisions is variation in the composition of a Class 2 chemical substance, and when that variation should result in the treatment of a substance as a new chemical substance. This issue is not always resolvable in terms of "exact molecular structure," for the simple reason that Class 2 chemical substances do not have a single "exact molecular structure."

EPA does not interpret the nomenclature provisions as being equivalently problematic with respect to Class 1 chemical substance (i.e., raising equivalent concerns that EPA should be treating various novel Class 1 chemical substances as being on the Inventory because they are similar in molecular structure to

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[1] Some commenters have suggested that a recent TSCA petition (the BRAG petition) may be aligned with these bill provisions. But the BRAG petition asked EPA to *alter* the nomenclature provision addressed in 8(b)(3)(A)(ii) (the Soap and Detergent Nomenclature System). It is thus unclear why the BRAG petition should be viewed as aligned with the purposes of the Senate language. In any event, a requirement to "maintain" a system does not necessarily imply a requirement to freeze the system without alteration.

other Class 1 chemical substances that are on the Inventory). Serious implementation issues would arise if one were to amend the Senate bill so that every chemical substance in commerce needed to be defined in terms of an "exact molecular structure." EPA does not interpret current TSCA as currently requiring every chemical identity to be defined in terms of an exact molecular structure.

Legislative History Supports Commenters' Concerns about Alternative Interpretations

Commenters' characterization of the general objective of the nomenclature provisions (i.e., to reduce the need for PMNs to be filed) appears to be supported by the legislative history in the Senate Report. See, e.g., page 20: "Under TSCA, numerous nomenclature conventions exist. . . . It is the intent of the Committee that the provisions of section [8] related to nomenclature will resolve these issues. . . . The Committee believes this approach will also help enhance EPA's ability to evaluate substances from new sources against existing substances for equivalence, enabling similar substances to rely on the Inventory listing of an existing substance. . . . S. 697 maintains [the] authority [to list chemical substances on the Inventory by category] to ensure that minor modification or variations in the formulation or structure of a chemical substance that have insignificant health or environmental consequences would not be automatically subject to the notification requirements of section 5. The Committee believes that EPA's current policy of not requiring notification for variations in naturally-occurring substances or mixtures should generally be continued."

In general, it has been EPA's approach to list chemicals as precisely as the Agency is able to at the time of listing. It has not been EPA's approach to allow "similar" substances to rely on existing Inventory listings, or to allow substances with minor modifications from listed substances to forego section 5 review. (The Senate Report on page 20 suggests that a value of the nomenclature provisions is that they will help prevent duplicative safety assessments and determinations by ensuring that substantially similar substances are considered at the same time, as appropriate. However, EPA does not see a connection between the nomenclature issues and the safety assessment and determination process, since nothing in the bill prevents EPA from assessing similar but different substances simultaneously.)

This history would tend to undercut an EPA interpretation that the nomenclature provisions have no impact, other than to require continuation of certain long-standing EPA nomenclature practices.

Statutory Mixtures

With respect to the "statutory mixture" provision, 8(b)(3)(A)(ii), the text of the provision does not actually set forth clear directions requiring EPA to depart from prior interpretation of the six listed chemical definitions. The intent behind this provision may be to broaden the scope of chemicals covered under the concept of statutory mixtures, but the effect of the language is difficult to gauge. EPA would probably interpret the language as effecting no change in the implementation of these six listings. But the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six. And the imprecise wording of what is covered even within the six ("treat all components of categories that are considered to be statutory mixtures under this Act") creates the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures. Moreover, even if the identified language were clarified, the argument might be raised, with support from the legislative history referenced above, that this provision was

intended to resolve certain issues, raising questions as to whether EPA's likely interpretation would prevail. Commenters on the bill have noted disputes between EPA and stakeholders about where the bounds of statutory mixtures lie. These disputes are germane, but the bill does not actually have the effect of clearly resolving them.

Arguments that Nomenclature Provisions Might Be Applied to Resolve Various Specific Naming Disputes

Some commenters have expressed concern about how the text of the nomenclature provisions in the Senate bill might be applied to alter the treatment of chlorinated paraffins, nanoscale materials, or micro-organisms under TSCA. EPA cannot predict exactly how the Senate bill language would be applied. EPA should receive judicial deference in its interpretation and implementation of the provisions. It is possible that EPA could confront arguments that 8(b)(3)(A)(iii), 8(b)(3)(B)(i), or 8(b)(3)(B)(ii) resolve various naming questions in industry's favor, but EPA's position would likely be that 8(b)(3)(A)(iii) is inapplicable (paraffins/nanoscale materials/micro-organisms are not statutory mixtures); 8(b)(3)(B)(i) is inoperative (no triggering guidance exists); and 8(b)(3)(B)(ii) is also inoperative (no duplicate listings exist).

Counter-arguments could be raised, though. A significant uncertainty in these provisions is what statements on multiple nomenclature might be cited by various stakeholder groups as guidance, and argued to constrain EPA's discretion in developing follow-up guidance under 8(b)(3)(B)(i). EPA would argue that only *EPA guidance* qualifies, and presumably that any EPA statement addressing nomenclature would have to have been issued at a sufficiently high level within the Agency to qualify as guidance, but the drafting is not clear in this regard. In addition, the legislative history referenced above could undercut an EPA position that there are no guidance documents allowing for multiple nomenclature conventions, and that 8(b)(3)(B)(ii) is also inoperative because no duplicate listings exist.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 22, 2016 6:02 PM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request on section 8 nomenclature language
Attachments: Nomenclature (3-21).docx

Michal – while understanding the TA request's urgency, given schedules and the specific technical and legal knowledge required on nomenclature, we need to hold off responding fully until Monday. We have concerns about (B)(i) and need more time to articulate them. Please let me know right away if that is a problem.

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the TSCA inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include byproducts that do not appear on the TSCA inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

Response: Although not able to fully respond yet, we have several concerns, including that the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six, creating the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

Response: EPA has no concerns with the (B)(ii) language

We continue to work on this TA request, please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Sent: Monday, March 21, 2016 7:08 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: Time-sensitive on section 8

Sven

Can you pls rush the review of this redlined text to portions of section 8?

Here are the basic questions:

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the tsca inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include biproducts that do not appear on the tsca inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

I think there is a desire to get this to the House asap.

Thanks
M
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

(iii) treat the categories of combinations considered to be statutory mixtures under this Act, and their components when present in such mixtures, as being included on the list established under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation--

or

(iii) include on the list established under paragraph (1), under the Chemical Abstracts Service numbers for the respective categories, the combinations considered to be statutory mixtures under this Act, and their components when present in such mixtures, including, without limitation—~~treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—~~

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—~~If an existing guidance allows for multiple nomenclature conventions, t~~The Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance determined by the Administrator, following a request by a manufacturer or processor that the Administrator review information reasonably available to the Administrator, to appear~~ing~~ multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall ~~develop guidance~~ recognize~~ing~~ the multiple listings as a single chemical substance.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Saturday, March 12, 2016 11:36 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on section 14 CBI in the House Offer
Attachments: HEC.TSCA TA.Section 14 CBI.docx; ATT00001.htm

Michal,
Attached please find TA as requested on the section 14 CBI provisions in the House offer. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

We are trying to compare this provision with other disclosure penalty provisions that exist in other statutes administered by EPA. We are aware of EPCRA and SDWA provisions, some restrictions on the way RMP data is disclosed, etc., but probably lack a full awareness/understanding of their similarities/differences.

Could you pull the examples of other provisions that create penalties for disclosure of CBI that are included in EPA statutes and give us some basis to compare them with what is in House section 14, along with any problems/limitations/workability concerns that may have been unintended/experienced in those existing statutes? Happy to get any concerns about the way that House provision might be expected to work as well.

***

EPA is aware of penalties for the release of CBI that are established under TSCA, FIFRA, and the CWA. Also, in some cases the release of CBI could be the basis for criminal liability under the Trade Secrets Act, which is referenced in several other EPA statutes (e.g., the Clean Air Act). EPA has not observed implementation problems arising with respect to these disclosure penalty provisions. The House bill retains the disclosure penalty provisions of current TSCA § 14(d).

The prosecution of any criminal violation of the statutes would fall under the jurisdiction of the Department of Justice.

***

FIFRA § 14

(f) Penalty for disclosure by Federal employees.

(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $ 10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 of the United States Code **[Ed: The Trade Secrets Act]** shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act. Nothing in this Act shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.

CWA § 308

(b) Availability to public; trade secrets exception; penalty for disclosure of confidential information. Any records, reports, or information obtained under this section (1) shall, in the case of effluent data, be

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

related to any applicable effluent limitations, toxic, pretreatment, or new source performance standards, and (2) shall be available to the public, except that upon a showing satisfactory to the Administrator by any person that records, reports, or information, or particular part thereof (other than effluent data), to which the Administrator has access under this section, if made public would divulge methods or processes entitled to protection as trade secrets of such person, the Administrator shall consider such record, report, or information, or particular portion thereof confidential in accordance with the purposes of section 1905 of title 18 of the United States Code **[Ed: The Trade Secrets Act]**. Any authorized representative of the Administrator (including an authorized contractor acting as a representative of the Administrator) who knowingly or willfully publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information which is required to be considered confidential under this subsection shall be fined not more than $ 1,000 or imprisoned not more than 1 year, or both. Nothing in this subsection shall prohibit the Administrator or an authorized representative of the Administrator (including any authorized contractor acting as a representative of the Administrator) from disclosing records, reports, or information to other officers, employees, or authorized representatives of the United States concerned with carrying out this Act [33 USCS §§ 1251 et seq.] or when relevant in any proceeding under this Act [33 USCS §§ 1251 et seq.].

Trade Secrets Act, 18 USC § 1905

Whoever, being an officer or employee of the United States or of any department or agency thereof, any person acting on behalf of the Federal Housing Finance Agency, or agent of the Department of Justice as defined in the Antitrust Civil Process Act (15 U.S.C. 1311-1314), or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5 publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 29, 2016 9:00 AM
To: 'Freedhoff, Michal (Markey)'; 'Black, Jonathan (Tom Udall)'; Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA Request on Section 14(b)

Michal,
This TA responds to the request on section 14(b) CBI.

Question - on the list in 14(b) of information generally protected from disclosure - are any of the items on the list items that EPA would currently not consider as CBI (unless it was publicly available etc)?

Response – We believe the information specified in section 14(b) would generally be protected from disclosure under current TSCA section 14 (assuming, as you say, it was not publicly available or otherwise precluded from CBI treatment), with one exception: while sales information, as specified in 14(b)(2), would generally be protected from disclosure, marketing information is a vague term that could include even public advertising, which EPA would not consider CBI.

Note that this response is based on the assumption that the information in question is *not* submitted as part of a health and safety study or as part of other information addressed in section 14(c) of the bill and offer; section 14(c) of the bill (and, with respect to health and safety studies, section 14(b) of current TSCA), would determine the CBI status of such information.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 23, 2016 2:53 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall) ; Deveny, Adrian (Merkley)
Subject: TA request Section 14

Question - on the list in 14(b) of information generally protected from disclosure - are any of the items on the list items that EPA would currently not consider as CBI (unless it was publicly available etc)?

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 5:07 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on section 14
Attachments: Senate TA (as passed) - Section 14.docx

Michal,
This responds to your TA request on section 14. You already have our comprehensive TA on the Senate bill as passed including TA on section 14 - attached is a pullout from that on section 14. We didn't see anything major in the new draft, spotted some potential glitches and it needs conforming changes that we haven't had a chance to pull together. Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 4:37 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TA support

Thanks. Those sections likely next week now. I think we are headed to 14 next - if you have TA on House 14 prepared pls send.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)
Original Message

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) **Specific** aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"~~(7)~~"**(8)** Except as otherwise provided in this section, the specific identity of a chemical substance **prior to the date on which the chemical substance is first offered for commercial distribution**, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

"~~(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).~~

Commented [A1]: As we have previously pointed out, it makes no sense to condition presumptive protection on whether the information actually meets the CBI standard in (a). In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A2]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

Commented [A3]: The point of this provision presumably is to protect chem id in advance of an NOC, but some pre-NOC distribution would likely be considered offered for commercial distribution under TSCA (e.g., distribution for R&D).

Conversely, some post-NOC manufacturing, processing, and distribution might not qualify as "offer[ing]" the chemical to another party, and so arguably might not fall under this heading.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under

Commented [A4]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

section 6.

"~~(C)~~"**(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"~~(D)~~"**(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"~~(4)~~"**(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"~~(5)~~"**(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** 4 "~~(2)~~"**(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify:

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if~~—

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a

Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period~~ **subsections (a) and (d), unless**—

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or**

no longer qualifies for protection against disclosure under subsection (a). in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"**(C)** EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)**—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section **8(b)(5)**; or

Commented [A5]: Reference should be to 8(b)(5)(B) specifically – change to active status.

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

Commented [A6]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph** (A) ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF **INFORMATION.—Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from

Commented [A7]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A8]: Certified mail is a cumbersome form of notification.

disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (e)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is

the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

Commented [A9]: ***This provision is confusing. The "information" in question would already have been submitted to EPA, so how would EPA be able to determine the format and language of the information? Also, subsection (g) already provides the timeframes for release of the info, so what more would EPA do to allow for expedient and swift access?

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—** **Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, **modifying or** denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Commented [A10]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approving, approving in part, or denying"

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 28, 2016 7:31 PM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Markey TSCA TA Request on senate section 16

Michal,

This TA responds to the inquiry on section 16 of the senate proposal.

Request: A question has arisen about a change to TSCA section 16 that is in the senate offer – attached and pasted below. I don't think any of us on this email were involved in its original drafting, and someone mentioned to us that they believed EPA TA may have been received on the specific change. Ringing any bells? At first glance, I'm not sure the change is needed given the changes made to Senate offer 15 (pasted below, and I believe accepted by House at this point). Any disagreement or concerns from you?

The section 16 change

(a) CIVIL.—(1) Any person who violates a provision of section 15 or 409 shall be liable to the United States for a civil penalty in an amount not to exceed $37,500 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of [redacted]

The section 15 offer (which I think was all or mostly House bill text)

SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

(1) fail or refuse to comply with any requirement of this title or any rule promulgated, order issued, or consent agreement entered into under this title, or any requirement of title II or any rule promulgated or order issued under title II;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 11.

[15 U.S.C. 2614]

Response: From a drafting perspective, it is more precise to have the second sentence read "constitute a separate violation of section 15 or 409," than read "constitute a separate violation of this Act." This is because the violations at issue are already specified (in the first sentence) to be violations of "section 15 or 409." Adopting the more precise drafting choice would also be consistent with current TSCA.

Changing "section 15 or 409" to "this Act" in the second sentence would accomplish nothing but it would be harmless. A violation of section 15 or 409 can be referred to as a violation of TSCA, since both of these provisions are part of TSCA.

Whether or not certain changes are accepted to section 15 shouldn't affect the above drafting analysis.

EPA doesn't recall providing prior TA on this specific issue, although we had previously provided TA about a separate issue: the consequences of making the first sentence of section 16 include all violations of "this Act."

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 24, 2016 6:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: senate section 16

Sven

A question has arisen about a change to TSCA section 16 that is in the senate offer – attached and pasted below. I don't think any of us on this email were involved in its original drafting, and someone mentioned to us that they believed EPA TA may have been received on the specific change. Ringing any bells? At first glance, I'm not sure the change is needed given the changes made to Senate offer 15 (pasted below, and I believe accepted by House at this point). Any disagreement or concerns from you?

Thanks

michal

The section 16 change

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The section 15 offer (which I think was all or mostly House bill text)

SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

(1) fail or refuse to comply with any requirement of this title or any rule promulgated, order issued, or consent agreement entered into under this title, or any requirement of title II or any rule promulgated or order issued under title II;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 11.

[15 U.S.C. 2614]

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, December 16, 2015 5:35 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on Unreasonable Risk

Michal,
This responds to your technical assistance request on "unreasonable risk." Please let me know if any questions. Thanks,
Sven

Question: If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

EPA Response: TSCA section 4 provides two bases for requiring testing: a finding the a chemical substance may present unreasonable risk (4(a)(1)(A)), and a finding based on production volume, release and/or exposure (4(a)(1)(B)). You previously asked whether the section 4 findings could be made for ubiquitous chemicals, and our answer was that they likely could under (B), but only for chemicals manufactured at substantial volumes. We understand that you now want to know if a change to the (A) findings would provide another, perhaps more certain, basis to require testing for ubiquitous chemicals.

We think it would, if by "ubiquitous" you mean a chemical with widespread exposure. If the (A) finding were changed to require only a showing that EPA has a basis for concern, we believe that language – plus the fact that Congress intentionally moved away from the "may present" standard – would give EPA a good basis to require testing of such a chemical in the absence of information demonstrating that the chemical posed little or no hazard. EPA would still need to show that there are insufficient data and experience as to the chemical to enable the Agency to determine or predict the effects of the chemical, and that testing is necessary to close the data gaps – findings that EPA must make under both (A) and (B) (4(a)(1)(A)(ii) and (iii), 4(a)(1)(B)(ii) and (iii)). But, again, for a chemical with widespread exposure, we think EPA would most likely be able to demonstrate a basis for concern so long as the Agency could show that there were open questions about hazard.

You also suggest the possibility of simply dropping the "may present" standard, rather than replacing it. We don't think that would make sense, since the (A) basis for testing would have no function if it contained no standard.

Finally, you asked whether or not EPA would be likely to use section 4, if given the authority, to help clear the hurdle to initiating a risk evaluation under section 6 of the House bill. We would not want to rule out this use of section 4 authority, but think such use would be fairly minimal, particularly in the earlier years of implementation when the focus would be on TSCA Work Plan chemicals and other chemicals that for which there is some information. EPA would interpret the bar for initiating a risk evaluation on non-Work Plan chemicals under 6(b)(3)(A)(i) as fairly low. The House language requires that EPA make a finding that the chemical substance "may present an unreasonable risk," but that finding is based on potential hazard and a potential route of exposure. We interpret this as not requiring actual or documented hazard/exposure information. And because we don't anticipate the 6(b)(3)(A)(i) finding to be a significant barrier to initiating risk evaluations, we also don't anticipate a regular need to invoke section 4 testing authority to overcome it. A more

likely use of section 4 would be to support necessary analysis during the risk evaluation, and ultimately, a determination of whether or not the chemical substance "presents or will present...an unreasonable risk."

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, December 06, 2015 9:53 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: TA request (for starting on Monday)

Nichole

We've very much appreciated the rapid turn around on questions related to the "may pose an unreasonable risk" section 4 and 6 text of House/TSCA, as well as efforts to understand what it could mean for EPA to have to determine both potential exposure and potential hazard under section 6 before starting a risk evaluation.

I'm trying to understand whether the solution on section 6 could be in section 4.

If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, February 02, 2016 5:01 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request- section 5 scope of preemption

Michal,
This responds to your TA request below.

Are there examples of chemicals that EPA imposed some sort of restriction on (either through a PMN consent agreement with a single manufacturer or through a SNUR to all potential manufacturers of that chemical) that, after EPA obtained more data once the chemical had been in commerce for some time, turned out to pose much greater or different risks than EPA initially believed existed at the time the first PMN was submitted/reviewed? Were any of these chemicals subsequently regulated by States once these added/new risks became known? Any and all examples are welcome – I'm trying to turn my concerns about that House provision into a real world example if one or more exist.

EPA Response:
One of the major components of the fire retardant product Firemaster 550 came through the TSCA new chemicals program before all of the concerns for this class of chemicals had become clear. EPA regulated some aspects of its use (e.g., not allowing releases to surface water) but did not address others, such as human health hazards and potential exposure, that we would now flag for further assessment and action based on more recent information.

Several states have either put restrictions on these chemicals, or have proposed to do so. For example, Minnesota enacted legislation to prohibit the manufacture, sale, offer for sale, or distribution for sale or use of children's products and furniture containing a minimum quantity of flame-retardant chemicals. California is currently reviewing flame retardants when used in furnishings or in building products, including ingredients in Firemaster 550, to investigate whether they should be subject to their Safer Consumer Product Regulations. This process in California is focused on determining if safer substitutes are available.

This technical assistance is provided in response to a congressional request and is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill language and comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, January 15, 2016 1:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request- section 5 scope of preemption

Sven

I'm interested in seeing whether there are any real-world examples that could illustrate potential problems with House scope of preemption for new chemicals.

Are there examples of chemicals that EPA imposed some sort of restriction on (either through a PMN consent agreement with a single manufacturer or through a SNUR to all potential manufacturers of that chemical) that, after EPA obtained more data once the chemical had been in commerce for some time, turned out to pose much greater or different risks than EPA initially believed existed at the time the first PMN was submitted/reviewed? Were any of these chemicals subsequently regulated by States once these added/new risks became known? Any and all examples are welcome – I'm trying to turn my concerns about that House provision into a real world example if one or more exist.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 15, 2016 6:46 PM
To: 'Freedhoff, Michal (Markey)'; Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA request- section 12(a)(2) and (3)

Michal,
This TA responds to your request on sections 12(a)(2) and 12(a)(3).

Previously you noted that the conforming changes to 12(b) were useful. What about the changes to 12(a)(2) or 12(a)(3)? These have been argued to place limitations on existing epa practice/authority.

Response: 12(a)(2) is not placing limitations on existing EPA practice; it is actually expanding EPA's jurisdiction over "export only" chemical substances. Note that under current TSCA, EPA has very limited jurisdiction over chemical substances that are manufactured solely for export. In order to apply the full panoply of TSCA tools to such substances (e.g., essentially anything other than reporting rules under TSCA section 8), EPA must make a preliminary finding under current 12(a)(2) that the substance "will present an unreasonable risk."

The Senate bill clarifies that these unreasonable risk determinations are without consideration of cost or non-risk factors, and it furthermore establishes a more relaxed standard ("likely to present an unreasonable risk") for asserting full TSCA jurisdiction over new chemical substances proposed for export only (12(a)(2)(A)), or the export-only manufacture of existing chemicals that were previously flagged as likely to present an unreasonable risk when they previously came through the new chemicals review process (12(a)(2)(C)). (Note, however, that the cross-reference to section 5(d)(4) is a "broken link" and needs to be updated to reflect the new paragraph structure of the Senate offer.)

The changes to 12(a)(3) could be read as conditioning EPA authority. EPA would not interpret them as imposing a substantive limitation on EPA authority, but they could be read differently. Under TSCA currently, if EPA make the unreasonable risk finding under 12(a)(2) for a chemical, regulation would attach to the chemical itself, and to any mixtures or articles containing the chemical, without any further action or determination. Sec 12(a)(3) adds an additional step before the regulated status of such mixtures and articles is clear. We believe the better reading of the provision would require EPA to make a determination as to such mixtures and articles – such that EPA's only choice is to fully regulate them or regulate them at specified concentrations. However, some might argue that it should be read as giving EPA the discretionary authority to address mixtures and articles, such that if EPA declined to do so in conjunction with a given 12(a)(2) determination, such mixtures and articles would not be regulated under TSCA.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 15, 2016 at 3:01:50 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Cc: "Black, Jonathan (Tom Udall)"

<Jonathan_Black@tomudall.senate.gov>, "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Subject: TA request section 12

Sven

Previously you noted that the conforming changes to 12(b) were useful.

What about the changes to 12(a)(2) or 12(a)(3)? **These have been argued to place limitations on existing epa practice/authority.**

Thanks
Michal
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 15, 2016 4:09 PM
To: 'Freedhoff, Michal (Markey)'; Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Sen. Merkley, Markey and Udall TSCA TA request - combined CBI on exemptions and partial bans

Adrian, Michal and Jonathan,
This TA responds to your questions about CBI and exemption and partial bans. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

If EPA imposes a single-use ban, but allows the continuation of a separate, critical use under Senate 6(g), would it be sufficient to protect the CBI for that critical use by simply adding at the end of 14(c)(3) ", except for chemical substances for which EPA has provided a critical use exemption under section 6(g)"?

Also, for Senate Sec.14(c)(3), how would this language on disclosure in the event of a "ban or phase out" apply for chemicals that are manufactured for export only? If EPA banned a chemical under Sec 6, would that also include a ban on the domestic manufacture for export purposes only? And if not, would CBI be disclosed or protected in that case?

Follow on similar to Adrian's first q - what if EPA established a ban or phase out on a use of a chemical but not on all uses. Would disclosure of CBI related to the one use have the potential to adversely impact the competitive posture of the manufacturer?

Response: As we understand your questions, you are referring to the following provision of the Senate offer:

> *(3) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.*

We do not think the language you suggest would accomplish what we understand to be your objective.

We note that there is some uncertainty as to the scope of section 14(c)(3) and how it would operate in the case of a ban or phaseout for particular uses. The provision is triggered by a ban or phaseout of the manufacture, processing, or distribution in commerce of a chemical substance. It is not clear if only a complete ban or phaseout of one of these activities triggers the provision, or if it would also be triggered by a ban or phaseout for certain uses. Since section 6(d)(3) contemplates bans and phaseouts for particular uses, the better reading is probably that the provision would be triggered by such partial bans or phaseouts. However, the provision appears to void CBI protection for the chemical as a whole (subject to 14(g)), not just for particular uses. So the issue we understand you to be raising – preserving claims associated with uses that are not banned or phased-out – appears to arise for any partial ban or phaseout, irrespective of whether an exemption is granted.

With respect to your suggested language: it also speaks in terms of the chemical substance, not the use. So, if any critical use exemption is granted, your language would apparently void operation of 14(c)(3) for the chemical as a whole, not just as applied to the use.

With respect to exports: chemical substances that are manufactured, processed or distributed solely for export are exempt from TSCA requirements unless EPA finds the chemical will present an unreasonable risk in the United States (TSCA section 12(a)). While EPA has not addressed this question under current TSCA, arguably section 14, including the release provisions in 14(c)(3), would not apply to chemical substances manufactured solely for export.

From: "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Date: March 14, 2016 at 6:43:04 PM EDT
To: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>, "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Subject: TSCA TA request - CBI

Sven
I have two additional Sec 14 TA requests—

If EPA imposes a single-use ban, but allows the continuation of a separate, critical use under Senate 6(g), would it be sufficient to protect the CBI for that critical use by simply adding at the end of 14(c)(3) ", except for chemical substances for which EPA has provided a critical use exemption under section 6(g)"?

Also, for Senate Sec.14(c)(3), how would this language on disclosure in the event of a "ban or phase out" apply for chemicals that are manufactured for export only? If EPA banned a chemical under Sec 6, would that also include a ban on the domestic manufacture for export purposes only? And if not, would CBI be disclosed or protected in that case?

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 16, 2016 12:34 PM
To: Black, Jonathan (Tom Udall)
Cc: Deveny, Adrian (Merkley); Freedhoff, Michal (Markey)
Subject: Sen. Udall TSCA TA On Sec. 26

Jonathan,
we have no issues to flag on the sec 26 changes. Please let me know if any additional questions. Thanks,
Sven

Would like to check with you on the impact of making these changes to the Senate offer...

26(b)(4) do the following:

- Include such amounts as are deposited in the Fund under this paragraph with (4)(A)
- Strike (4)(A)(ii) and (iii)
- Strike (B)(ii)(III) [I know our intent it to section off TSCA money, but I'm not sure what it means]
- Strike (4)(C)
- Add House passed (b)(3)(e) "Accounting and Auditing"
- We have already taken their "Auditing" language and struck ours.
- They are keeping our "Termination" language

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 22, 2016 1:29 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA Request on Cost Consideration Options
Attachments: Udall.TSCA TA.Cost Consideration Options.docx

Jonathan,
This TA responds to your phone request for cost consideration options based on the House bill. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Two versions of revision to House bill language, hewing closest to that language

Version 1: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed **population.**

Version 2: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective than the other requirements considered by the Administrator, except where the Administrator determines that one or more of the other requirements ~~requirements described in subsection (a) that are in~~ addition to or different ~~from the cost-effective~~ requirements the Administrator ~~was able to identify during the rulemaking process~~ are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

Version 3 – more substantial revision to House bill language, to establish a preference rather than a presumption

(B) generally give preference to requirements that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective.

Commented [A1]: Note that we have not attempted to integrate the revisions into the Senate construct – e.g., we have not referenced back to subsection 4(b)(4)(A) to define "unreasonable risk". Conforming changes can be made if there is a desire to proceed with one of these approaches.

Commented [A2]: Compared to the House bill version, this version clarifies that: 1. The scope of EPA's analysis is limited to the information described under subsection (A) (which includes "reasonably ascertainable economic consequences"); 2. (B) does not drive an open-ended requirement to identify all potentially cost-effective protective requirements; and 3. the requirements selected must eliminate the identified unreasonable risk. It does not "flip the presumption" in favor of cost-effective remedies, though; it weakens the presumption.

Commented [A3]: This version has the features described in Version 1, plus the added feature of presenting cost-effectiveness as a relative concept. This necessitated a fair amount of rewording, because it clarifies up front that only the range of options considered by EPA is at play.

Commented [A4]: This is a softer version of 6(c)(1)(B). It establishes a general preference for more cost-effective requirements. EPA believes its decision to impose less cost-effective requirements could be subject to legal challenge, and that EPA would need to explain why it overcame the preference. But we believe the Agency's bar for doing so would be lower than the bar under the version above.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 25, 2016 12:22 PM
To: Black, Jonathan (Tom Udall); Albritton, Jason (EPW); 'Freedhoff, Michal (Markey)'; Deveny, Adrian (Merkley); Zimmerman, Melissa (Appropriations)
Subject: Sen. Udall TSCA TA Request on fees
Attachments: Fees - 3-24-16.pdf

Jonathan,
This responds to the TA request on proposed fees language.

Question: can we have your team review the attached language on fees to identify any workability problems and identify areas that would help EPA collect/use fees.

EPA Response: The statutory language change in section 26(b)(3) of TSCA under the House offer is very similar to and consistent with the statutory language EPA provided in TA to the Senate on March 11. We do not see issues presented by the slight difference in the language.

However, a parallel change in language needs to be made to the House offer language amending section 26(b)(1). Otherwise, conflicting language will exist in the Act and it is highly likely that the agency's ability to use fees would be constrained by the narrower statutory language in the House offer regarding section 26(b)(1).

In Section 10(1)(C) of the House offer, language is proposed for the first sentence of 26(b)(1) to replace the words "the Act" with the words "the provision of this title for which such fee is collected." That language needs to be changed to be consistent with the new language proposed by the House for section 26(b)(3). We would propose that the language be changed to "to defray the cost of administering the provision for which such fee is collected and of any other activities under the Act related to the chemical substance or mixture that is the subject of the data submission or risk evaluation."

In the absence of this parallel change, the apparent intent underlying the change to section 26(b)(3) would not be achieved.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 24, 2016 5:39 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Albritton, Jason (EPW) <Jason_Albritton@epw.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Zimmerman, Melissa (Appropriations)

<Melissa_Zimmerman@appro.senate.gov>
Subject: Proposal on fees

Sven, can we have your team review the attached language on fees to identify any workability problems and identify areas that would help EPA collect/use fees.

Thanks,
---Jonathan

SEC. 10. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (b)(1)—

(A) by striking "of a reasonable fee";

[(B) by inserting ", or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary" after "section 4 or 5";]

(C) by striking "this Act" and inserting "the provision of this title for which such fee is collected";

(D) by striking "Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100." and inserting "Such rules shall provide for lower fees for small business concerns."; and

[(E) by striking "submit the data and the cost to the Administrator of reviewing such data" and inserting "pay such fee and the cost to the Administrator of reviewing such data or conducting such risk evaluation, as applicable";]

(2) by adding at the end of subsection (b) the following:

"(3) FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a revolving fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the 'Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

"(B) COLLECTION AND DEPOSIT OF FEES.—The Administrator shall collect the fees described in paragraph (1) and deposit those fees in the Fund.

"(C) CREDITING AND AVAILABILITY OF FEES.—On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, in carrying out the provisions of this title for which the fees are collected under paragraph (1).

"(D) USE OF FUNDS BY ADMINISTRATOR.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation [~~for use only in administering the provisions of this title for which the fees are collected~~.] [for use in defraying the cost of administering the provision for which such fee is collected and of any other activities under the Act related to the chemical substance or mixture that is the subject of the data submission or risk evaluation]

"(E) ACCOUNTING AND AUDITING.—

"(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

"(ii) AUDITING.—

"(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

"(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

"(aa) the fees collected and amounts disbursed under this subsection;

"(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of the title for which the fees are collected; and

"(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(3)(A)(ii).

"(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit."; and

connecting to EPA affirmative decisions.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 21, 2016 1:21 PM
To: 'Black, Jonathan (Tom Udall)'
Subject: Sen. Udall TSCA TA Request on New Chemicals and Senate Proposal
Attachments: Udall.TSCA TA.New Chemicals - compare to Senate.docx

Jonathan,
Please see the attached document that responds to your TA request for a comparison between the New Chemicals program and the Senate proposal. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 17, 2016 9:55 AM
To: Kaiser, Sven-Erik
Subject: New Chemicals and Senate Proposal

Hi Sven, is it possible to get some kind of compare and contrast on the Senate Proposal for Section 5 with the way the current new chemicals program is being run?

Some way to show what is similar/different from current Administration practice?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

New Chemicals – Section 5
Current EPA Practice vs. Senate Offer

The following is a description of how the new chemicals program operates under current TSCA, with some notes on how the program would or would not change under the Senate offer:

- **Manufacturers are required to submit a premanufacture notice (PMN) to the Agency prior to manufacturing a new chemical, or a chemical for a use which EPA has determined to be a "significant new use."**
    - This requirement remains the same under Senate offer
- **The receipt of the PMN starts a 90-day time period during which no manufacturing can occur. This period may be extended by EPA for up to 90 days, or suspended with agreement of the submitter for development of further information.**
    - This is generally the same under the Senate offer. However, the Senate offer would allow EPA to shorten this period in the event EPA finds that the chemical meets the standard in section 5(d)(2)(B).
- **Although EPA is not required to evaluate new chemicals for safety under current law, it does so routinely. EPA's practice is to evaluate the chemical within the 90-day period, and to take additional action as appropriate. If EPA takes no further action, however, manufacturing can simply commence upon expiration of the 90-day time period.**
    - The Senate offer amends TSCA to *require* such evaluation, and one of three affirmative findings: (A) that the chemical is likely to present an unreasonable risk, (B) that the chemical is not likely to present unreasonable risk, or (C) that more information is necessary. These findings trigger specific required actions by EPA.

Difference in the Senate Offer to note:

- **Significant new use of chemical in an article or category of articles**
    - The Senate offer requires that, prior to issuing a SNUR for a chemical in an article or category, EPA must find that the "reasonable potential for exposure to the chemical substance through the article or category of articles…warrants notification." No such additional finding is required to regulate chemicals articles under current law.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 17, 2016 1:33 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: SEPW TSCA budget request

Dimitri – below are the most recent budget numbers. – See p. 502 in the Congressional Justification - http://www.epa.gov/sites/production/files/2016-02/documents/fy17-congressional-justification.pdf. Let me know if you want to discuss – today is bad but Wendy could do something first thing tomorrow morning if helpful.
Thanks,
Sven

Sven-Erik Kaiser
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Toxic Substances: Chemical Risk Review and Reduction
Program Area: Toxics Risk Review and Prevention
Goal: Ensuring the Safety of Chemicals and Preventing Pollution
Objective(s): Ensure Chemical Safety

(Dollars in Thousands)

	FY 2015 Actuals	FY 2016 Enacted	FY 2017 Pres Bud	FY 2017 Pres Bud v. FY 2016 Enacted
Environmental Program & Management	***$58,721.1***	***$58,554.0***	***$67,186.0***	***$8,632.0***
Total Budget Authority / Obligations	$58,721.1	$58,554.0	$67,186.0	$8,632.0
Total Workyears	225.1	238.7	248.7	10.0

From: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>
Date: February 17, 2016 at 11:00:09 AM EST
To: Sven Kaiser <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TSCA budget request

Sven, I keep seeing different numbers in what you all have requested both this year and last year for TSCA (within the Chemical Risk Review and Reduction). In FY 17 for example I have seen the number $62.4 as well as $67.2. For FY 2016 I have seen both $69 million and $56.3 million.

Can you all quickly get back to me on what exactly the budget request was last year for TSCA activities (even if it is within two programs) and what it is this year?

Happy to talk with someone if it is helpful and easier to explain.

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of **subsections (a)** and (d) shall be presumed to be protected from disclosure, **subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law**:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance **prior to the date on which the chemical substance is first offered for commercial distribution**, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g)~~.

Commented [A1]: As we have previously pointed out, it makes no sense to condition presumptive protection on whether the information actually meets the CBI standard in (a). In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A2]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

Commented [A3]: The point of this provision presumably is to protect chem id in advance of an NOC, but some pre-NOC distribution would likely be considered offered for commercial distribution under TSCA (e.g., distribution for R&D).

Conversely, some post-NOC manufacturing, processing, and distribution might not qualify as "offer[ing]" the chemical to another party, and so arguably might not fall under this heading.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"~~(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"~~(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of~~ **clause (ii)—**

"~~(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

"~~(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"~~(II)~~**"(bb)** any chemical substance or mixture for which—

"~~(aa)~~**"(AA)** testing is required under section 4; or

"~~(bb)~~**"(BB)** a notification is required under section 5; or

"~~(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

"~~(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

"~~(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

"~~(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

"~~(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

"~~(A)~~**"(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).**

"~~(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under

Commented [A4]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

section 6.

"~~(C)~~"**(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"~~(D)~~"**(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"~~(4)~~"**(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"~~(5)~~"**(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** 4 "~~(2)~~"**(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a

Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or**

no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"**(C)** EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall —~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)**—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section **8(b)(5);** or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

Commented [A5]: Reference should be to 8(b)(5)(B) specifically – change to active status.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, **modify,** or deny the claim or request.

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

Commented [A6]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator **denies or modifies a claim or request under paragraph (1), intends to release information pursuant to subsection (e), or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance**, the Administrator shall notify, in writing and by **certified mail**, the person that submitted the claim of the intent of the Administrator to release the information.

Commented [A7]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A8]: Certified mail is a cumbersome form of notification.

"(B) RELEASE OF **INFORMATION.—Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from

disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (e)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (e)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is

the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

Commented [A9]: ***This provision is confusing. The "information" in question would already have been submitted to EPA, so how would EPA be able to determine the format and language of the information? Also, subsection (g) already provides the timeframes for release of the info, so what more would EPA do to allow for expedient and swift access?

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—** **Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, **modifying or** denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Commented [A10]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approving, approving in part, or denying"

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 14, 2016 3:45 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: SEPW TSCA TA Fees Question

Dimitri,
This TA responds to your followup question on fees.

Question:
An issue was raised last week with this paragraph because of its reference to no obligation under FACA. This is something I don't believe has ever been raised by EPA TA. Any thoughts or concerns? I am trying to dig up where we pulled the language from but if you all have any experience with similar language in other statutes that works it would be helpful to know. Makes perfect sense to me that EPA would meet with the people subject to fees to ensure everything works for all parties, having other groups who have nothing to do with the fees is does not seem necessary.

Response:
EPA had previous conversations with Senate staff on this issue and walked through the PRIA legislative development process led by stakeholders. Based on those conversations, it was clear there was not enough time for such a detailed process to occur for TSCA. The formulation in the Senate bill was created to still allow EPA to involve those persons subject to paying fees.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, March 14, 2016 12:04 PM
To: Kaiser, Sven-Erik
Subject: Fees Question

An issue was raised last week with this paragraph because of its reference to no obligation under FACA. This is something I don't believe has ever been raised by EPA TA. Any thoughts or concerns? I am trying to dig up where we pulled the language from but if you all have any experience with similar language in other statutes that works it would be helpful to know. Makes perfect sense to me that EPA would meet with the people subject to fees to ensure everything works for all parties, having other groups who have nothing to do with the fees is does not seem necessary.

> "(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 14, 2016 3:58 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: SEPW TSCA TA on chem id v. molecular structure #4

Dimitri – additional TA on chem id CBI claims. We are working on more specific info on declassifications that could be ready tomorrow.

4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.

Response: In 2015, EPA received just over 400 TSCA Section 8(e) health and safety studies. Of those, just over 200 of the submissions claimed chem id as CBI. The majority of 8(e) submissions relate to R&D chemicals, pesticide chemicals, or chemicals not in commerce. Over the last few years, the CBI chem id claims for 8(e) submissions has been around 50%. EPA continues to review 8(e) submissions for the chemicals in commerce and take steps to declassify unwarranted CBI claims as appropriate.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Monday, March 14, 2016 2:35 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: URGENT - SEPW TSCA TA on chem id v. molecular structure

Dimitri – TA on chem id. Please see responses except #4. We're working on #4 and will get you what numbers we have as soon as possible. Note that the responses to #1 and #6 may have changed slightly from what I sent earlier. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

1. Is it EPA's view that molecular structure is a component or element of chemical identity that may, but does not necessarily, unambiguously describe a chemical substance? In other words, does chemical identity include chemical molecular structure?

40 CFR 720.45 states that a specification of the chemical identity "includes" specifying: "For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained."

2. Can a structurally descriptive generic name for a chemical substance unambiguously describe the chemical?

Not always. For examples, chemical substances of unknown or variable composition or biological material (UVCBs) are not described structurally.

3. Does EPA provide guidance on structurally descriptive generic names that enables an unambiguous description of a chemical substance? Is the Agency currently updating that guidance, or does it have plans to revise it?

EPA has guidance for generic names. However, a generic name, by definition, is designed to have broader applicability, as opposed to a chemical ID that identifies a specific chemical substance. There are no current plans to update this guidance.

Here is the link to the guidance:
https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf

4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.

Working on the response

5. Existing Section 14(b) excludes process and mixture information from disclosure in a health and safety study. Other confidential information in a health and study, such as company identity or chemical identity, are not explicitly excluded from disclosure, but are also not explicitly targeted for disclosure (particularly since section 14 directs EPA to only disclose the non-confidential portion of information that contains a mix of confidential and non-confidential information). Do either the House or Senate provisions amending section 14 change this interpretation in any way?

Current section 14 only governs what may not be disclosed. Inherent in that is that when CBI and non-CBI are mixed we may disclose only what is not CBI. And in some of our regulations we require that CBI be explicitly identified.

The House bill language on chemical identity in health and safety studies would be a departure from current 14(b), which at the very least allows chem ID to be disclosed as part of a health and safety study when its disclosure would not in turn disclose portions of a mixture or process information (and the Agency goes further, arguing in some cases that chem ID is always part of a health and safety study).

6. Does EPA read "molecular formula" being different than "molecular structure?"

Yes. Compare 40 CFR 720.45(a)(1)(iii) (requirement to include "molecular formula" in a PMN) and 40 CFR 720.45(a)(1)(iv) (requirement to include the "chemical structure diagram"). Two different chemical substances may have the same molecular formula, and yet have different molecular structures.

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, March 14, 2016 12:23 PM

To: Schmit, Ryan <schmit.ryan@epa.gov>
Subject: RE: EPA TA on chem id v. molecular structure

Also Ryan – maybe a quick question that could be helpful if getting through some of the other ones isn't as fast. In the Senate bill, (b)(8) of Section 14 goes to the protection of chemical identity and includes language saying "including the chemical name, molecular formula, CAS number..." Does EPA read "molecular formula" being different than "molecular structure?"

From: Karakitsos, Dimitri (EPW)
Sent: Monday, March 14, 2016 12:08 PM
To: 'Schmit, Ryan'
Subject: RE: EPA TA on chem id v. molecular structure

Thanks Ryan, this is very helpful but I have a few follow up questions. We are meeting with the House to discuss at 2pm so any quick feedback would be incredibly helpful but getting some answers anytime would be good to inform the discussion going forward. Much appreciate the help.

1. Is it EPA's view that molecular structure is a component or element of chemical identity that may, but does not necessarily, unambiguously describe a chemical substance? In other words, does chemical identity include chemical molecular structure?
2. Can a structurally descriptive generic name for a chemical substance unambiguously describe the chemical?
3. Does EPA provide guidance on structurally descriptive generic names that enables an unambiguous description of a chemical substance? Is the Agency currently updating that guidance, or does it have plans to revise it?
4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.
5. Existing Section 14(b) excludes process and mixture information from disclosure in a health and safety study. Other confidential information in a health and study, such as company identity or chemical identity, are not explicitly excluded from disclosure, but are also not explicitly targeted for disclosure (particularly since section 14 directs EPA to only disclose the non-confidential portion of information that contains a mix of confidential and non-confidential information). Do either the House or Senate provisions amending section 14 change this interpretation in any way?

From: Schmit, Ryan [mailto:schmit.ryan@epa.gov]
Sent: Friday, March 11, 2016 1:57 PM
To: Karakitsos, Dimitri (EPW)
Subject: EPA TA on chem id v. molecular structure

Dimitri, per your request for TA on this issue:

In general terms, we believe "chemical identity" is best understood as a reference to information that would allow a person to unambiguously specify which substance entry on the TSCA Inventory they are referring to, whereas "molecular structure" is a reference to chemically descriptive information about the molecule itself (e.g., the atoms present in a molecule, their connections to each other, and their spatial arrangement). All chemical substances on the TSCA Inventory have a chemical identity. Some UVCB chemical substances on the TSCA Inventory may lack a known molecular structure.

"Molecular identity" appears only in the definition of what a particular chemical substance is. It is not itself defined. As EPA has used the term, it relates to the demarcation of one chemical substance from another. See: http://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf.

"Chemical identity" and "molecular structure" are listed as separate items in the list of types of information that EPA may require reporting on under Section 8(a)(2). Similarity of "molecular structure" is also one of the grounds to categorize chemical substances under section 26. The terms are not defined in the statute.

Thanks,
Ryan

Ryan N. Schmit
Special Assistant to Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention (OCSPP)
Telephone: 202-564-0610
Email: schmit.ryan@epa.gov

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 22, 2016 12:53 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: SEPW TSCA TA on Nomenclature
Attachments: SEPW.TSCA TA.Nomenclature.docx

Dimitri,
The attached TA responds to the request on nomenclature. Please let me know if any additional questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, March 15, 2016 5:02 PM
To: Kaiser, Sven-Erik
Subject: Nomenclature questions

Sven – have a few nomenclature follow up questions for you all.

In 8(b)(3)(B)(ii) we require the development of guidance recognizing multiple listings – would it be EPA developing that guidance? Wouldn't this guidance presumably allow EPA the discretion to determine when to recognize any duplicative listings as a single substance?

Does EPA recognize that there are multiple listed names for some chemicals on the inventory? Are chemicals like tallow fatty acid with a carbon chain of 16-18 represented more than once?

The oleochemical folks for example believe that there are possibly thousands of redundant inventory listings on the inventory, does EPA believe there are none?

Thanks

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

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SEPW 3/15/16 TA Request on Nomenclature

Question: In 8(b)(3)(B)(ii) we require the development of guidance recognizing multiple listings – would it be EPA developing that guidance? Wouldn't this guidance presumably allow EPA the discretion to determine when to recognize any duplicative listings as a single substance?

EPA Response: 8(b)(3)(B)(ii) requires the development of guidance, but that duty is contingent on the existence of multiple entries on the TSCA Inventory. Where there are no multiple entries, there would be no duty to develop any guidance at all. EPA is not aware of any multiple entries on the TSCA Inventory. If multiple entries were found, EPA expects that it would simply delete any duplicate entries and forgo developing any guidance at all. EPA does not need to develop a guidance document in order to have authority to delete a duplicate entry under the Inventory. EPA already has that authority under 8(b)(1): "compile, keep current, and publish"

To the extent there is guidance development under 8(b)(3)(B)(ii), such guidance would be developed by EPA. Note however: to the extent there is guidance development under 8(b)(3)(B)(i), that EPA guidance development effort is potentially subject to a requirement under 8(b)(3)(B)(i)(II)(bb) to harmonize with existing guidance documents under 8(b)(3)(B)(i). We would argue that any such other guidance documents are limited to EPA guidance documents, and presumably that any EPA statement addressing nomenclature would have to have been issued at a sufficiently high level within the Agency to qualify as guidance. EPA is unaware of any such documents and would therefore most likely argue this provision addresses a null set, but it is not certain that EPA would prevail if a party were to point to an EPA or other document that it alleges constitutes a guidance within the meaning of the bill.

Question: Does EPA recognize that there are multiple listed names for some chemicals on the inventory? Are chemicals like tallow fatty acid with a carbon chain of 16-18 represented more than once?

Response: No, EPA is not aware that the same chemical substance is listed more than one time under multiple names listed on the TSCA Inventory. The example given is not precise, but it appears to be a description of a single chemical substance that presumably has a single CAS number. The issue that 8(b)(3)(B)(ii) deals with is a circumstance where there are two chemical substances, currently listed with two different names and two different CAS numbers, that are in fact that same chemical substance, that should be treated as only having one name and one CAS number. EPA is not aware of any actual examples of that scenario.

Question: The oleochemical folks for example believe that there are possibly thousands of redundant inventory listings on the inventory, does EPA believe there are none?

Response: EPA is not aware of any redundant listings. We remain willing to consider any evidence to the contrary that any stakeholder group may wish to present.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 12:13 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: SEPW TSCA TA on nomenclature

Dimitri, this responds to your TA request on nomenclature. Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

1. **Is the Senate nomenclature language, both Class 2 and statutory mixtures, simply codifying EPA's current practice with regards to those substances?**

   EPA interprets section 8(b)(3)(A)(i) as a requirement to continue its current practice of allowing Class 2 chemical substances to be named and listed as discrete entries on the TSCA Inventory. EPA also interprets this provision as allowing EPA to retain technical discretion to ensure that Class 2 chemical naming is done correctly.

   Similarly, EPA interprets section 8(b)(3)(A)(ii) as a requirement to continue its current practice of allowing Class 2 chemical substances to be named according to the SDA nomenclature system. EPA also interprets this provision as allowing EPA to retain technical discretion to ensure that SDA naming is done correctly.

   EPA interprets section 8(b)(3)(A)(iii) as a statutory ratification of the scopes of these particular Inventory listings, as listed in the TSCA Inventory, in a manner consistent with appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a). However, the phrase "including, without limitation" could be interpreted to broaden the scope of statutory mixtures currently recognized by EPA. If the intent is to simply codify EPA's current practice, it should be clarified that the list of (I) through (VI) is an exclusive list. Further, while EPA can interpret the phrase "all components of categories that are considered to be statutory mixtures under this Act," the phrasing is awkward and it could be improved to reduce the chance of confusion. The following would be clearer: "all chemical substances described by the following category listings, when manufactured as described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)."

   EPA's interpretation of 8(b)(3)(B) is that this provision is wholly inoperative, since EPA is not aware of any "existing guidance" that would trigger 8(b)(3)(B)(i), or duplicate listings on the Inventory that would implicate 8(b)(3)(B)(ii). If this provision is not inoperative, the legislative history in the Senate Committee Report reflects a clear intent that it do something other than merely codify EPA's current practices. Specifically, the Report asserts on page 20 that currently "numerous nomenclature conventions exist that may prevent the efficient distribution of chemicals into commerce," and it explains that the nomenclature provisions "will resolve these issues" by establishing new requirements for EPA. The Report also indicates that the nomenclature provisions will "enable[] similar substances to rely on the Inventory listing of an existing substance." This appears to be a reference to narrowing the scope of substances that will require review under Section 5, due to nomenclature changes.

2. **Is EPA aware of widespread (or any instances) where current Class 2 or statutory mixture language has been abused or used to circumvent Section 5 by allowing entirely new chemicals to market without going through the pmn process?**

   EPA has taken a limited number of enforcement actions related to overly broad interpretation of the coverage of Class 2 chemicals on the Inventory. In addition, many manufacturers have sought confirmation from EPA that chemicals they intend to manufacture are covered by Class 2 chemicals on the Inventory and not subject to PMN requirements. In many of these cases, the Agency has responded that PMNs would be required.

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, March 03, 2016 1:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA on nomenclature

Sven – there seems to be continued confusion over the Senate's nomenclature provisions. I know you all are working on a lot for us and we appreciate it but wanted to ask if someone could fairly quickly respond to two specific questions that are designed to be easy answers.

1. Is the Senate nomenclature language, both Class 2 and statutory mixtures, simply codifying EPA's current practice with regards to those substances?
2. Is EPA aware of widespread (or any instances) where current Class 2 or statutory mixture language has been abused or used to circumvent Section 5 by allowing entirely new chemicals to market without going through the pmn process?

Any help with this would be much appreciated.

Thanks,

Dimitri

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 11, 2016 5:52 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: SEPW TSCA TA request on Inventory Reset
Attachments: SEPW.TSCA TA.Inventory Reset.docx

Dimitri,
The attached document responds to your TA request on the inventory reset. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, February 09, 2016 9:54 AM
To: Kaiser, Sven-Erik
Subject: TA request

Morning Sven,

Hope everything is going well. Wanted to see if you all could give me thoughts or language on a few things in Section 8 of the Senate TSCA bill.

First would be how to possibly redraft the inventory reset provision. Its design was merely for EPA to publish the current inventory and through a simple hand raising exercise break it up into an "active" and "inactive" list based on responses from manufacturers and processors. What it was not supposed to do (and there seems to be a lot of concern and confusion) is create some massive reporting requirement where every use had to be registered or every company had to duplicate submittals – if one manufacturer or processor says something is active, that is it and it goes on the active list and everyone else is absolved of any responsibilities. This is not where EPA should be registering uses or getting all its exposure information, it is just to split the list into two categories in the easiest way possible.

Additionally I would be curious to get EPA's thoughts on whether 10 years is preferred/necessary for the time period going back or would something like 5 likely be sufficient for an "active" substance? This is also supposed to help inform the agency but not create some sort of retroactive penalty provision where if someone forgot they manufactured something 9 years ago and not 10 they get fined by the agency. 10 years may just be too long a timeframe.

Finally, there has been some concern that although we intended a simple notification to be required to move a chemical substance from the inactive list back to the active list this may be viewed as requiring a more stringent notification that was intended possibly even under Section 5. This again was not the intent, it was merely to let EPA know a chemical is now active and being manufactured so they should consider it eligible for prioritization and review as necessary. Any thoughts on how to make clearer this is just another hand raising exercise?

Any thoughts/assistance would be much appreciated and I am happy to discuss if folks are interested.

Thanks,

Dimtiri

Dimitri J. Karakitsos
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Senate Committee on
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We are not aware of any provision under § 8(b)(4) whereby the manufacturers and processors of chemical substances would be required to report information on a use-by-use basis or report any information on the uses of their chemical substances. The reference to "non-exempt commercial purpose" is a regulatory exemption for persons who may have manufactured or processed. but solely for non-commercial or exempt commercial purposes (e.g., non-isolated intermediates or R&D).

As EPA understands the current drafting. the information to be reported would be limited to:

- A notification that the submitter has manufactured or processed the chemical substance in the last 10 years. (§ 8(b)(4)(A))
- An indication whether the submitter wishes to maintain any existing claim it may have that the identity of the chemical substance is CBI. (§ 8(b)(4)(B)(ii))
- To the extent such CBI claims are being maintained. upfront substantiation for the claims.

Note: Because the hand-raising exercise is linked to a parallel program whereby EPA must affirmatively review (subject to some carve-outs) all the CBI claims for Chem ID being maintained (§ 8(b)(4)(D)) two raised hands for the same chemical substance are not necessarily duplicate submittals. This is because there may be Chem ID CBI claims at issue. If so. one party may wish to maintain its CBI claims even if another does not. Two parties may submit separate substantiation to maintain their separate CBI claims.

Appended to this TA are drafting changes that we believe accomplish the intent of your request: avoiding the imposition of any new reporting requirements and avoiding the need for more than one manufacturer or processor. per chemical substance. to "raise a hand" as a part of the reset process.

But we have not attempted to resolve the problems that these changes generate in connection with the CBI review provisions under section 8(b)(4). These could be addressed in a variety of ways. For example. the bill could establish a two-phase system where manufacturers and processors first go through the hand-raising exercise and then later go through a separate CBI re-assertion process if their chemical finds its way onto the active TSCA Inventory. We could

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provide further drafting assistance on this issue but we would need more direction regarding your intended objectives.

[2.] Additionally I would be curious to get EPA's thoughts on whether 10 years is preferred/necessary for the time period going back or would something like 5 likely be sufficient for an "active" substance? This is also supposed to help infarm the agency but not create some sort of retroactive penalty provision where if someone forgot they manufactured something 9 years ago and not 10 they get fined by the agency. 10 years may just be too long a timeframe.

EPA does not have strong feelings on a 10-year versus a 5-year period of lookback for "active" chemical substances.

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We do not understand why a notice under section 8(b)(5) is being viewed by some as a "more stringent" notice than a PMN or SNUN, under section 5. The only information that is necessary is that the person intends to manufacture or process the chemical for some non-exempt commercial purpose. The particular non-exempt commercial purpose need not be identified. Unlike a PMN or SNUN, there is no requirement to submit additional information bearing on hazard, or conditions of use, or reasonably anticipated exposures.

As with the original inventory reset, there is a requirement here to notify and substantiate CBI claims for chemical identity which are being maintained. This is related to the parallel CBI review provisions of section 8(b)(4), as noted earlier.

***

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall establish a procedure whereby~~require~~ manufacturers and processors may~~to~~ notify the Administrator, ~~by not later than 180 days after~~ the date ~~of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has~~ that they have manufactured or processed a chemical substance on the list published under paragraph (1) for a nonexempt commercial purpose during the 10-

Commented [A1]: Deadline is unnecessary since reporting is voluntary, and if anyone sends in a "late" submission for a chemical substance EPA would just add the chemical to the active list.

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Assumptions:

1. As of Last SNUR publication date of June 5, 2015
2. Counted by FR Publication Date
3. Includes Final /Direct Final Rules
4. Includes New and Existing Chemical Substances
5. Counted by 40 CFR Citations
6. Does not count Withdrawn Chemical Substances

	Fiscal Year	Calendar Year
2005	0	1
2006	2	1
2007	85	87
2008	2	45
2009	80	35
2010	56	57
2011	2	34
2012	278	346
2013	147	47
2014	85	102
2015	77	59
Total	814	814

Does EPA believe this option a) works

Yes, EPA believes this provision could be implemented. EPA would need to establish whether or not the restrictions in the rule are cost-effective in order to implement "(A) Public Availability," but this analysis would be "under paragraph (1)" and thus bounded by considerations of practicability and reasonably available information. Whether or not the restrictions are found to be cost-effective would control whether EPA has a further duty to include additional descriptive analysis in the administrative record. A key difference with old options ## 3 and 4 relates to whether the necessity discussion is framed as a free-standing determination (as in options ## 3 and 4) or as an integral part of the justification of the proposed rule (as in your draft). Given that the rejection of more direct language on determining cost-effectiveness would be part of the legislative history, Courts would likely construe your proposed text as a signal to give a slightly greater degree of discretion to EPA on the finding (of cost-effectiveness or necessity) than would be afforded under the House bill.

and b) adds to the analytic burden and litigation risk as compared to old option #2 (and if so, how)?

Yes, this language adds to analytic burden relative to old option #2. EPA would need to decide whether the restrictions in the rule were cost-effective, which was not a decision mandated under old option #2. Note also that this language apparently requires EPA to determine whether *each restriction* is cost-effective, not whether the rule as a whole is cost-effective; option #2 in contrast appears to require analysis of the rule as a whole. Furthermore, if a restriction were not cost-effective, EPA would need to develop an analysis of an indeterminate number of alternatives in order to decide whether the restrictions were nonetheless necessary (again, though, bounded by the practicability and reasonable availability limitations).

Yes, this rule adds to the litigation risk relative to old option #2. EPA would need to defend decisions that particular restrictions are cost-effective, or nonetheless necessary, whereas it would not need to do so under old option #2. It is possible, but it cannot be predicted with confidence, that this formulation would entail less litigation risk than old option #3 (i.e., the slightly modified version of House language on cost effectiveness).

Some additional observations:

1. **We note that the inclusion of "mixtures" in this language – which is in TSCA section 6(c) but not in the cost-consideration provisions of either bill – may cause confusion, since section 6 rulemaking under the bills appears to be limited to chemical substances that have been found to present unacceptable risk, not to mixtures per se.**
2. **As the text is reorganized from S 697, (d)(1)(D)(ii) seems awkward, since it is not clear how the costs and benefits of alternative regulatory action would be relevant to the economic consequences of the regulatory action actually selected.**

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 2:10 PM
To: 'Freedhoff, Michal (Markey)'
Subject: TSCA TA - Section 6 Issue

Michal,
In reviewing bill text (house and senate passed bills), EPA just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments.

As you know, EPA has been working on risk assessments (draft and final) for a number of chemical substances - TCE, NMP, MC, and 1-BP. These risk assessments have been scoped relatively narrowly, so as to focus the Agency's resources on uses most likely to present risk. EPA is *not* looking at all the conditions of use for these chemicals.

This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses.

Should the House/Senate construct become law, the Agency would be left with a difficult choice in moving forward with our ongoing Work Plan assessment and rules.

One option might be to move forward with finalizing the risk evaluation and regulating a subset of chemical uses. There's some risk that the new law would not support such an interpretation. Even if it would, the risk management deadline for the chemical would start ticking immediately. That means that EPA would be on the clock to expand the risk evaluation to cover remaining non-scoped uses, finalize those determinations, AND complete a rulemaking to manage any associated risks. For risk assessments that are draft or final, this appears to be the public policy preferred option. It's highly unlikely that EPA would be able to complete this work for non-scoped uses within the statutory timeframes.

Alternatively, EPA could hold off on moving to risk management finalizing and spend additional time evaluating the full suite of uses. This would have the practical effect of allowing known risks to health or the environment (i.e., those identified in the narrowly-scoped assessment) to continue unregulated during this period.

We'd welcome an opportunity to work with you on a drafting solution to this issue, but wanted to bring to your attention as soon as possible.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
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- **Did anything in this offer address the specific concerns raised in EPA's January 20th letter? And if so, how?**

Yes, the offer appears to partially address certain concerns. First, the offer appears to partially address the concern that manufacturer priorities could overrun those of the Agency by confining the number of manufacturer-initiated risk evaluations to 25-50% of the total number of ongoing risk evaluations. EPA still has specific concerns on this point, as described in a later response. Second, the offer would seem to partially address the concern regarding funding by adding fee collection authority for EPA-initiated risk evaluations. However, the bill still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims.

- **Do any of the additions raise workability or implementation concerns?**

Yes. First, the additions reclassify a particular subset of industry requests under § 6(b)(3)(A)(ii) (relating to new chemical substances that have not yet been manufactured) as requests under § 5(i). This change makes these requests no longer subject to deadline adjustment under § 6(b)(5). Nor would such requests be subject to the new caps under § 6(b)(3)(C). Furthermore, EPA would not be able to collect fees for such requests if manufacture had not yet commenced (there would not yet be any manufacturer to against whom to assess risk evaluation fees under § 26(b)(1), and the authority to collect fees for the PMN review would not extend to cover voluntary risk evaluations. These provisions could create circumstances in which unfunded requests for voluntary risk evaluations overwhelm EPA's review capacity.

Second, the additions will require a very significant and resource-intensive implementation effort: (1) to sift through every CBI claim ever received under TSCA since the enactment of the statute; (2) to make a provisional adjudication of the qualifications of every claim; (3) to request and review re-substantiation packages where deemed warranted; (4) to notify all parties for which re-substantiation was inadequate, of pending release; and (5) to defend litigation arising from the required determinations. The implementation concerns raised by these provisions are rendered even more serious by the lack of funding for CBI review activities, and by the 5-7 year time frame specified for completing the specified CBI reviews, which could be enforced by deadline suits. Note that the Senate bill is considerably narrower in scope (only certain Chem ID claims), and it allows EPA to directly obligate CBI claimants to bring their claims (and re-substantiation) to EPA's attention, rather than creating the two-step process envisioned here. Note also that the Senate bill provides fee funding for these activities.

Third, specifying that alternative test protocols that avoid animal testing must be validated has the potential to significantly delay EPA's use of such protocols and divert EPA resources towards validation efforts. Validation as is currently implemented through Federal processes such as ICCVAM may not always be necessary depending on the context in which the alternative test method/data will be applied. While validation is recognized as an important process needed to accept an alternative method as a replacement for a whole animal test, there are circumstances under which alternative methods and the data derived from them may be valuable prior to completion of a full validation process. For

example, data from an alternative method may provide information or insights useful as part of a weight of evidence evaluation even when the method has not been fully validated as a replacement test.

- **Does the House discussion draft address the major concerns from the EPA Jan. 20th letter to ensure that safety decisions are made absent consideration of costs?**

Please note, as an initial matter, that EPA's letter did not articulate concerns that the House bill, as passed, would allow consideration of costs to factor into risk evaluations under section 6. In fact, EPA believes that the House bill – as passed and as modified recently - very clearly *excludes* consideration of costs from the both the risk evaluation and risk management triggering phases.

Rather, EPA's views letter pointed out potential inconsistencies in the application of the "unreasonable risk" safety standard elsewhere in the bill (in the risk management portions of section 6 and other sections of TSCA) which left ambiguity about the role of cost considerations in those contexts.

The bill does not attempt to address EPA's concerns on this point. For example, the bill does not provide an upfront safety standard definition or redefine "unreasonable risk" in each instance it appears. As such, there remains uncertainty as to what safety standard would apply for EPA actions under provisions of TSCA, outside of Section 6, that reference "unreasonable risk." The potential inconsistencies in risk management standards within Section 6 also remain (e.g., the standard for cost-effective v. non-cost effective requirements, and standards for regulating articles, replacement parts and PBTs).

- **Does the House draft ensure an affirmative safety finding for new chemicals?**

No, the new subsection 5(i) does not ensure that all new chemicals will receive an affirmative safety finding before the commencement of manufacture. It only applies if the person submitting the pre-manufacture notice for a chemical substance requests a risk evaluation of such substance. Subsection 5(i) is furthermore unnecessary to allow for this possibility. Such requests are already provided for under § 6(b)(3)(A)(ii).

- **Do the changes require EPA to review substantiation for past CBI claims?**

As described above, the changes require EPA to review all past CBI claims. EPA would then identify a particular subset of past CBI claims for which re-substantiation would be required and then EPA would request and review those re-substantiation packages.

With respect to the remaining CBI claims (i.e., those for which EPA did not require re-substantiation as an outcome of its initial review) the bill provides that such claims are automatically waived 10 years after enactment if re-substantiation is not sent to EPA by that time. The bill does not require that EPA review such re-substantiation, however.

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- **Do the changes ensure that industry-requested chemicals will not be expedited relative to chemicals that EPA selects itself?**

While the changes are in some respects helpful in addressing this issue, they do not ensure that the volume of industry-requested risk evaluations will be appropriately balanced against the volume of EPA-initiated risk evaluations. This is because:

- Section 6(b)(5)((B)(i) still appears to allow EPA to delay both EPA-initiated and industry-requested risk evaluations if the volume of industry-requested risk evaluations is excessive.
- Section 6(b)(7) still subjects the minimum number of EPA-initiated assessments to available appropriations.
- There is still no mechanism for industry fees to fund the development of risk management actions that EPA might be obligated to undertake as a consequence of industry-requested risk evaluations.
- As described above, a subset of industry-requested risk evaluations are now removed from caps and deadline adjustment (those accompanying a PMN).

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Two versions of revision to House bill language, hewing closest to that language

Version 1: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

Version 2: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective than the other requirements considered by the Administrator, except where the Administrator determines that one or more of the other requirements ~~requirements described in subsection (a) that are in addition to or different from the cost-effective~~ requirements ~~the Administrator was able to identify during the rulemaking process~~ are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

Version 3 – more substantial revision to House bill language, to establish a preference rather than a presumption

(B) generally give preference to requirements that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective.

Commented [A1]: Note that we have not attempted to integrate the revisions into the Senate construct – e.g., we have not referenced back to subsection 4(b)(4)(A) to define "unreasonable risk". Conforming changes can be made if there is a desire to proceed with one of these approaches.

Commented [A2]: Compared to the House bill version, this version clarifies that: 1. The scope of EPA's analysis is limited to the information described under subsection (A) (which includes "reasonably ascertainable economic consequences"); 2. (B) does not drive an open-ended requirement to identify all potentially cost-effective protective requirements; and 3. the requirements selected must eliminate the identified unreasonable risk. It does not "flip the presumption" in favor of cost-effective remedies, though; it weakens the presumption.

Commented [A3]: This version has the features described in Version 1, plus the added feature of presenting cost-effectiveness as a relative concept. This necessitated a fair amount of rewording, because it clarifies up front that only the range of options considered by EPA is at play.

Commented [A4]: This is a softer version of 6(c)(1)(B). It establishes a general preference for more cost-effective requirements. EPA believes its decision to impose less cost-effective requirements could be subject to legal challenge, and that EPA would need to explain why it overcame the preference. But we believe the Agency's bar for doing so would be lower than the bar under the version above.

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New Chemicals – Section 5
Current EPA Practice vs. Senate Offer

The following is a description of how the new chemicals program operates under current TSCA, with some notes on how the program would or would not change under the Senate offer:

- **Manufacturers are required to submit a premanufacture notice (PMN) to the Agency prior to manufacturing a new chemical, or a chemical for a use which EPA has determined to be a "significant new use."**
    - This requirement remains the same under Senate offer
- **The receipt of the PMN starts a 90-day time period during which no manufacturing can occur. This period may be extended by EPA for up to 90 days, or suspended with agreement of the submitter for development of further information.**
    - This is generally the same under the Senate offer. However, the Senate offer would allow EPA to shorten this period in the event EPA finds that the chemical meets the standard in section 5(d)(2)(B).
- **Although EPA is not required to evaluate new chemicals for safety under current law, it does so routinely. EPA's practice is to evaluate the chemical within the 90-day period, and to take additional action as appropriate. If EPA takes no further action, however, manufacturing can simply commence upon expiration of the 90-day time period.**
    - The Senate offer amends TSCA to *require* such evaluation, and one of three affirmative findings: (A) that the chemical is likely to present an unreasonable risk, (B) that the chemical is not likely to present unreasonable risk, or (C) that more information is necessary. These findings trigger specific required actions by EPA.

<u>Difference in the Senate Offer to note:</u>

- **Significant new use of chemical in an article or category of articles**
    - The Senate offer requires that, prior to issuing a SNUR for a chemical in an article or category, EPA must find that the "reasonable potential for exposure to the chemical substance through the article or category of articles…warrants notification." No such additional finding is required to regulate chemicals articles under current law.

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1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?

2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Cost Considerations in a Rule

❖ **"S 697"**

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

❖ **"MERGED HOUSE/SENATE PROPOSAL"**

d) PROMULGATION OF SUBSECTION (b) RULES.

(1) **REQUIREMENTS FOR RULE.**—In promulgating any rule under subsection (b) with respect to a chemical substance or mixture, the Administrator shall factor in the following considerations, and publish a statement describing how they were factored into the rule—

(A) the effects of ~~such~~ **the chemical** substance or mixture on health and the magnitude of the exposure of human beings to **the chemical** ~~such~~ substance or mixture;

(B) the effects of ~~such~~ **the chemical** substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture~~,~~**;**

(C) the benefits of ~~such~~ **the chemical** substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

(D)~~)~~ the reasonably ascertainable economic consequences of the rule, after consideration of

(i) ~~after~~ the **likely** effect ~~on~~ **of the rule on** the national economy, small business, technological innovation, the environment, and public health;~~.~~

(ii) the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. ;

(E) any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking. ;

❖ **"SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A).

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❖ **"SUPPLEMENTED SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A) **and shall consider whether the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator under subparagraph (A)(vi) are cost-effective.**

❖ **"H.R. 2576 AS MODIFIED USING EPA TA"**

(B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed population.

❖ **"H.R. 2576"**

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risks.

	Burden relative to baseline	**Litigation Risk**
S. 697	**Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Statement describing how analysis was taken into account is already a baseline requirement of administrative law.	**Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified.
Senate Offer	**Second Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces analytical burden.	**Second Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces the range of issues that might be the basis of litigation.

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	Burden relative to baseline	**Litigation Risk**
Merged House/Senate Proposal	**Third Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Requirement to "factor" considerations into a decisions and publish explanatory statement is already a baseline requirement of administrative law. No increase in burden from requirement to "consider and publish a statement"	**Third Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified. Relative to H.R. 2576, list of mandatory factors is more prescriptive, somewhat increasing litigation opportunities to claim EPA failed to consider one of the points.

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	Burden relative to baseline	**Litigation Risk**
Supplemented Senate Offer	**Fourth Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added. Overall, there is probably greater analytical burden in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in burden.	**Fourth Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added; Overall, there is probably greater litigation risk in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in litigation risk.

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	Burden relative to baseline	**Litigation Risk**
H.R. 2576 as modified by EPA TA	**Fifth Lowest Analytical Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces a requirement to determine that the selected option is cost-effective, or, if EPA selects a non-cost-effective option, to determine that there are no protective cost-effective options; but these analytic burdens are bounded by what is practicable based on the information already required to be considered in the rulemaking. Failure to meet the safety standard is clearly a basis to deem an alternative unacceptable. Arguably also implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Fifth Lowest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is some uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary, but this is moderated by the "practicable" language.

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	Burden relative to baseline	**Litigation Risk**
H.R. 2576	**Highest Introduced Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces the same analytic objectives as paragraph (B) as modified, but the analysis is less clearly bounded by the information already required to be considered in the rulemaking. Failure to meet the safety standard is very likely a basis to deem an alternative unacceptable. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Highest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 14, 2016 2:35 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: URGENT - SEPW TSCA TA on chem id v. molecular structure

Dimitri – TA on chem id. Please see responses except #4. We're working on #4 and will get you what numbers we have as soon as possible. Note that the responses to #1 and #6 may have changed slightly from what I sent earlier. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

1. Is it EPA's view that molecular structure is a component or element of chemical identity that may, but does not necessarily, unambiguously describe a chemical substance? In other words, does chemical identity include chemical molecular structure?

40 CFR 720.45 states that a specification of the chemical identity "includes" specifying: "For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained."

2. Can a structurally descriptive generic name for a chemical substance unambiguously describe the chemical?

Not always. For examples, chemical substances of unknown or variable composition or biological material (UVCBs) are not described structurally.

3. Does EPA provide guidance on structurally descriptive generic names that enables an unambiguous description of a chemical substance? Is the Agency currently updating that guidance, or does it have plans to revise it?

EPA has guidance for generic names. However, a generic name, by definition, is designed to have broader applicability, as opposed to a chemical ID that identifies a specific chemical substance. There are no current plans to update this guidance.

Here is the link to the guidance:
https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf

4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.

Working on the response

5. Existing Section 14(b) excludes process and mixture information from disclosure in a health and safety study. Other confidential information in a health and study, such as company identity or chemical identity, are not explicitly excluded from disclosure, but are also not explicitly targeted for disclosure (particularly since section 14 directs EPA to only disclose the non-confidential portion of information that contains a mix of confidential and non-confidential information). Do either the House or Senate provisions amending section 14 change this interpretation in any way?

Current section 14 only governs what may not be disclosed. Inherent in that is that when CBI and non-CBI are mixed we may disclose only what is not CBI. And in some of our regulations we require that CBI be explicitly identified.

The House bill language on chemical identity in health and safety studies would be a departure from current 14(b), which at the very least allows chem ID to be disclosed as part of a health and safety study when its disclosure would not in turn disclose portions of a mixture or process information (and the Agency goes further, arguing in some cases that chem ID is always part of a health and safety study).

6. Does EPA read "molecular formula" being different than "molecular structure?"

Yes. Compare 40 CFR 720.45(a)(1)(iii) (requirement to include "molecular formula" in a PMN) and 40 CFR 720.45(a)(1)(iv) (requirement to include the "chemical structure diagram"). Two different chemical substances may have the same molecular formula, and yet have different molecular structures.

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, March 14, 2016 12:23 PM
To: Schmit, Ryan <schmit.ryan@epa.gov>
Subject: RE: EPA TA on chem id v. molecular structure

Also Ryan – maybe a quick question that could be helpful if getting through some of the other ones isn't as fast. In the Senate bill, (b)(8) of Section 14 goes to the protection of chemical identity and includes language saying "including the chemical name, molecular formula, CAS number..." Does EPA read "molecular formula" being different than "molecular structure?"

From: Karakitsos, Dimitri (EPW)
Sent: Monday, March 14, 2016 12:08 PM
To: 'Schmit, Ryan'
Subject: RE: EPA TA on chem id v. molecular structure

Thanks Ryan, this is very helpful but I have a few follow up questions. We are meeting with the House to discuss at 2pm so any quick feedback would be incredibly helpful but getting some answers anytime would be good to inform the discussion going forward. Much appreciate the help.

1. Is it EPA's view that molecular structure is a component or element of chemical identity that may, but does not necessarily, unambiguously describe a chemical substance? In other words, does chemical identity include chemical molecular structure?
2. Can a structurally descriptive generic name for a chemical substance unambiguously describe the chemical?
3. Does EPA provide guidance on structurally descriptive generic names that enables an unambiguous description of a chemical substance? Is the Agency currently updating that guidance, or does it have plans to revise it?
4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with

confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.
5. Existing Section 14(b) excludes process and mixture information from disclosure in a health and safety study. Other confidential information in a health and study, such as company identity or chemical identity, are not explicitly excluded from disclosure, but are also not explicitly targeted for disclosure (particularly since section 14 directs EPA to only disclose the non-confidential portion of information that contains a mix of confidential and non-confidential information). Do either the House or Senate provisions amending section 14 change this interpretation in any way?

From: Schmit, Ryan [mailto:schmit.ryan@epa.gov]
Sent: Friday, March 11, 2016 1:57 PM
To: Karakitsos, Dimitri (EPW)
Subject: EPA TA on chem id v. molecular structure

Dimitri, per your request for TA on this issue:

In general terms, we believe "chemical identity" is best understood as a reference to information that would allow a person to unambiguously specify which substance entry on the TSCA Inventory they are referring to, whereas "molecular structure" is a reference to chemically descriptive information about the molecule itself (e.g., the atoms present in a molecule, their connections to each other, and their spatial arrangement). All chemical substances on the TSCA Inventory have a chemical identity. Some UVCB chemical substances on the TSCA Inventory may lack a known molecular structure.

"Molecular identity" appears only in the definition of what a particular chemical substance is. It is not itself defined. As EPA has used the term, it relates to the demarcation of one chemical substance from another. See: http://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf.

"Chemical identity" and "molecular structure" are listed as separate items in the list of types of information that EPA may require reporting on under Section 8(a)(2). Similarity of "molecular structure" is also one of the grounds to categorize chemical substances under section 26. The terms are not defined in the statute.

Thanks,
Ryan

Ryan N. Schmit
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